

**EXPERT REPORT OF JONATHAN E. GREENLEAF, M.D.
REGARDING NON-INFRINGEMENT**

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, I, Jonathan E. Greenleaf, M.D., an expert witness for Defendant Arthrex, Inc. (“Arthrex”), hereby set forth my expert report as follows.

I. QUALIFICATIONS AND PUBLICATIONS

My name is Jonathan Greenleaf and I am the same Jonathan Greenleaf who previously submitted an expert report on invalidity of the KFx Patents dated February 21, 2013, in this matter. My qualifications and publications are the same as those mentioned in my prior report and listed in my CV attached as Exhibit 1 to that report.

II. DATA AND INFORMATION CONSIDERED

My conclusions and opinions as set forth below are based on the data and information described below, on my review and analysis of the materials in Ex. 1, the Court’s claim construction Order, my testing conducted in this case, as well as my knowledge and experience with suture anchors and surgical procedures from my 22 years of practice in the field of orthopedic and arthroscopic surgery and research.

III. EXPERT TESTIMONY DURING PAST FOUR YEARS

My expert testimony during the past four years remains the same as that identified in my prior expert report dated February 21, 2013.

IV. COMPENSATION

My compensation for my time spent working on this case is the same as that mentioned in my prior report dated February 21, 2013.

V. SUMMARY OF MY OPINIONS

Based upon my experience, my review and consideration of the materials identified below, the materials identified in Ex. 1, and my testing conducted in this case, it is my opinion that surgeons using the accused methods do not infringe the KFx Patents either literally or under the doctrine of equivalents. It is also my opinion that even if surgeons are found to have directly infringed the KFx Patents, Arthrex should not be found liable for indirectly infringing the KFx Patents. It is further my opinion that Dr. Ticker's description of the non-infringing alternatives omits many obvious alternatives that would have been available to surgeons if the accused methods were not available in 2009 and that surgeons would have turned to those alternatives in the absence of the accused methods. It is also my opinion that Dr. Ticker's characterization of many alternative methods available in 2009 is incorrect.

VI. THE KFX PATENTS AND PROSECUTION HISTORY

I have reviewed KFx's infringement contentions and interrogatory answers and understand that KFx is asserting claims 1, 5-7, 11-12, 14-21, 23-25, and 28-30 of the '311 Patent against Arthrex. I also understand that KFx is asserting claims 1-7 and 9-19 of the '942 Patent and claims 1-7 and 13-17 of the '969 Patent against Arthrex.

The KFx patents cover a surgical method of attaching soft tissue to bone. Claim 1 of the '311 Patent, for example, covers a method of inserting a first suture anchor into bone through soft tissue and into the bone underneath the soft tissue. The suture attached to the first anchor is passed from the first anchor over the soft tissue. A second anchor is then inserted into the bone by screwing it into the bone adjacent to the soft tissue so that it is not underneath the soft tissue. The claim then requires that after the second anchor is inserted into bone, the suture attached to the first anchor is then tensioned to compress an area of tissue to bone between the edge of the

soft tissue and the first anchor. Lastly, after the second anchor is inserted into bone, the claims require that the suture be fixedly secured to the second anchor without tying any knots.

Claim 1 of the '942 Patent is similar to claim 1 of the '311 Patent except that rather than requiring the insertion of the second anchor, the '942 Patent requires insertion of a distal member of a second anchor into bone where the second anchor is made up of the distal member and a proximal member. After the distal member is inserted into the bone, claim 1 of the '942 Patent requires that the suture attached to the first anchor be tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. Lastly, after the suture is tensioned, the proximal member is moved toward the distal member in order to fixedly secure the suture at the second anchor position without tying any knots.

Claim 1 of the '969 Patent is also somewhat similar to claim 1 of the '942 Patent except that instead of inserting a distal member of a second anchor into bone, claim 1 of the '969 Patent requires inserting at least a portion of a second anchor into bone. After the at least a portion of the second anchor is inserted into bone, claim 1 requires that the suture attached to the first anchor be tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. After the suture is tensioned, the suture is fixedly secured at the second anchor position without tying any knots. Claim 1 of the '969 Patent then requires at least one of the anchors to have certain structural features; an anchor tip and a hollow cylinder, where the anchor tip has an aperture through which suture is threaded prior to inserting the anchor.

I describe below certain steps described in the KF_x Patents and in the provisional applications cited on the face of the KF_x Patents. I also describe a portion of the prosecution

history of the KFx Patents. All of these materials are publicly available and inform a person of ordinary skill in the art¹ about the scope of the inventions described in the KFx Patents.

A. Inserting a First Anchor Into Bone

The KFx Patents describe two types of anchors; a medial (first) anchor and a lateral (second) anchor. The medial anchor is described as the “tissue and bone piercing anchor” (column 9, line 59) and the lateral anchor is described as the “suture capturing anchor” (column 4, line 58). As for the medial (tissue and bone piercing) anchor, there is only one way it is described as being inserted into the bone; trans-tendon, or through the soft tissue.

The tissue and bone piercing anchor is described as having “a first configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.” Column 9, line 65 – column 10, line 4. This is achieved by the design of the anchor, which is shaped like a nail having a small diameter so as not to cause damage to the tissue while passing through.

The specification of the KFx Patents also describes that the tissue and bone piercing anchor has a “hollow cylinder having portions of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions . . . [to] prevent the anchor from being easily removed from the bone after deployment.” Column 10, lines 5-11. The anchor is also described as having “a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone.” Figures 10A and 10B of the KFx Patents are shown below and illustrate

¹ In my prior report dated February 21, 2013, I opined regarding who a person of ordinary skill in the art was during the 2004 timeframe. My opinion remains the same as previously stated for purposes of this opinion.

the first and second configurations achievable with the hollow cylinder that deforms to form lateral protrusions.

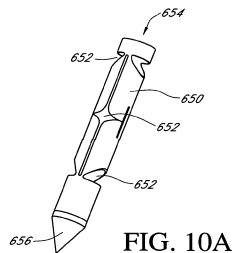


FIG. 10A

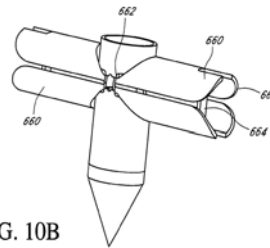


FIG. 10B

This description of the first anchor piercing (or passing through) the soft tissue is repeated at least 12 times throughout the specification. See, for example, Abstract (“also described is a soft tissue and bone piercing anchor”); column 2, lines 19-21 (“the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue”); column 2, lines 38-41 (“the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone”); column 4, lines 11-13 (“the procedure involves inserting the medial bone anchor 20 with suture 10 pre-attached through the soft tissue”); lines 39-41 (“the medial bone anchors 20 are designed so that they can be easily pierced through the soft tissue 12 and bone 16”); lines 55-57 (“accordingly, described below are . . . anchors adapted to easily pierce through soft tissue and bone”); column 10, line 60-61 (describing “a bone anchor adapted for piercing through the soft tissue and into underlying bone”); column 10, lines 23-24 (stating, referring to Figure 10A, “on the other end, a pointed tip 656 is disposed allowing the anchor to pierce through soft tissue and bone”); column 12, lines 54-57 (with reference to Figure 16A, stating “the piercing anchor 800 attached to an anchor inserter 802 as described above is pierced through soft tissue 804 that had become detached from underlying bone 806”); column 13, lines 38-39 (“a first anchor with a suture pre-attached is

inserted through the soft tissue and into the bone”); lines 41-42 (“the first anchor is inserted by directly piercing the soft tissue”); lines 59-61 (“this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone”).

Figures 16B and 16C are shown below and depict the medial anchor being inserted into the bone through the soft tissue and then deforming to stay securely within the bone. There is no description within the KFx Patents of inserting the medial anchor any way other than going through the soft tissue and into the bone.

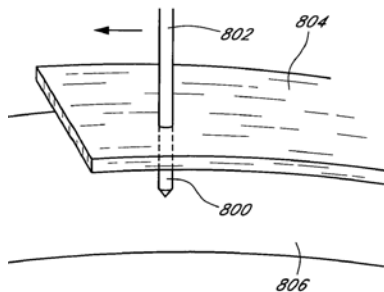


FIG. 16B

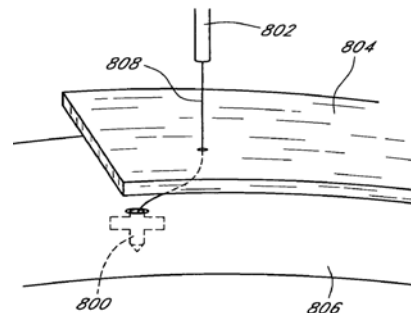
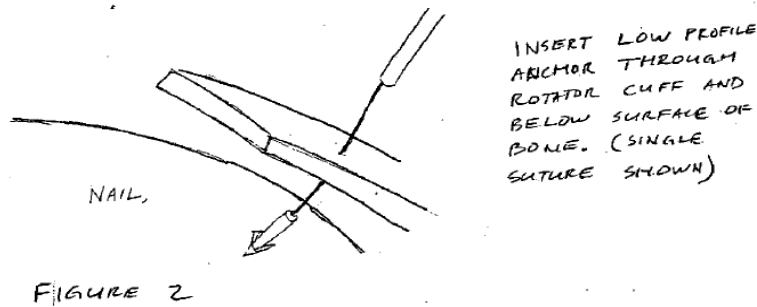


FIG. 16C

This trans-tendon technique of inserting the medial anchor is also described in the provisional application dated September 17, 2004, which includes pages from KFx’s inventor lab notebook. The notebook pages describe only one method for inserting the medial anchor into the bone; trans-tendon, stating “insert low profile anchor through rotator cuff and below surface of bone.” DDX 115 at KFX0002136. The lab notebook, describing Figure 2, further states “during deployment, the low profile anchor punctures through the rotator cuff and the anchor is positioned sub-surface to the bone.” DDX 115 at KFX0002141. Figure 2 from the lab notebook is shown below. There is no description within the lab notebooks of inserting the medial anchor any way other than going through the soft tissue.



- B. Inserting a Second Anchor (or a Distal Member of the Second Anchor, or at Least a Portion of the Second Anchor) Into Bone and Fixedly Securing the Suture to the Second Anchor (or at the Second Anchor Position)

The KFx Patents describe a two-piece anchor having an anchor base 100 and an anchor top 200. The anchor base is first screwed into the bone so that it is securely fixed in the bone. The inserter is then retracted to expose the suture securing mechanism within the second anchor.

In operation, the suture attached to the first anchor is tensioned to compress the tissue back to the bone. Then after the surgeon is satisfied with the suture tension, the suture is fixedly secured to the second anchor (or “at the second anchor position” for the ‘942 and ‘969 Patents) by ratcheting down the anchor top onto the anchor base and locking the suture between the two anchor portions.

The specification describes this as the suture securing mechanism being deployed to capture the suture. According to the specification, “the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon) . . . the suture can be moved into the mechanism without threading an end of the suture into the mechanism.” Column 4, line 61 – column 5, line 3. And as the Court noted in its claim construction Order, the specification defines “fixedly secured” as “the suture within the suture securing mechanism cannot be easily moved relative to the bone anchor.” Order Construing claims, Oct. 10, 2012 at 4 (citing column 5, lines 5-7). The specification

further states that “the two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces.” Column 5, lines 12-14. The two-piece anchor is shown below at Figs. 6A and 16E of the KFx Patents.

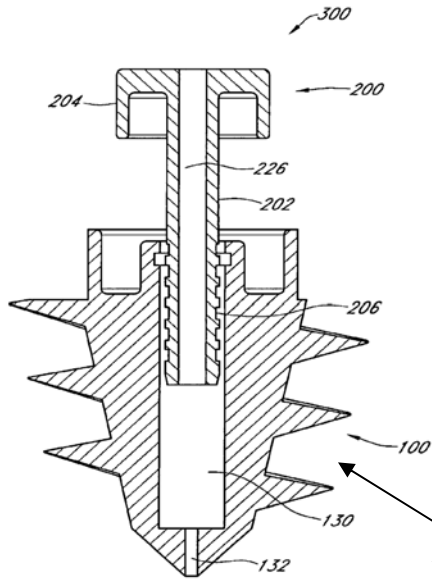


Fig. 6A

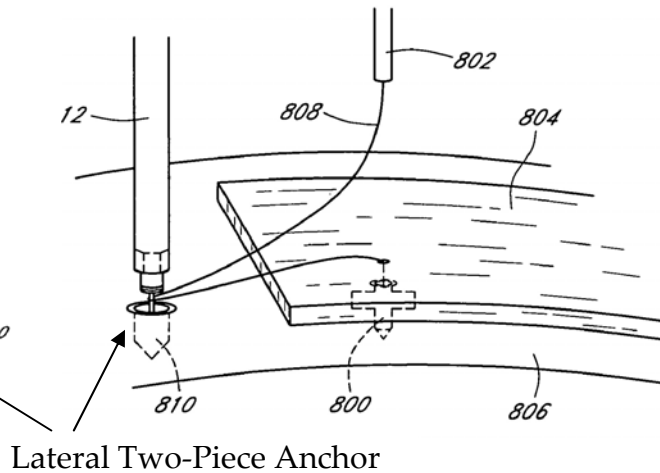


Fig. 16E

The KFx Patents describe that when the anchor top 200 is ratcheted all the way down into the central bore of the anchor base, passageways 302 and 304 are formed between the two anchor portions. These passageways 302, 304 are where the suture is captured and compressed so that it is securely attached to the anchor. Column 7, lines 56-65 and column 13, lines 3-12. The passageways 302, 304 formed when the anchor top 200 is ratcheted all the way into the anchor base 100, are shown below in Fig. 6B of the KFx Patents. And the suture wedged between the two anchor portions is shown below in Fig. 16F of the KFx Patents. There is no description in the KFx Patents of attaching the suture to the second anchor other than capturing the suture in the suture capturing mechanism between the two anchor portions.

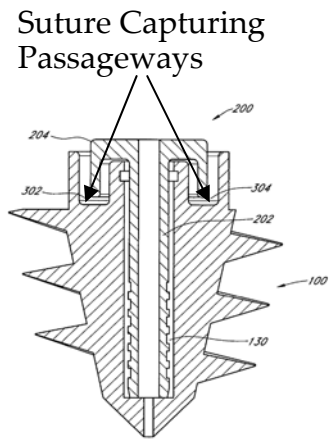


Fig. 6B

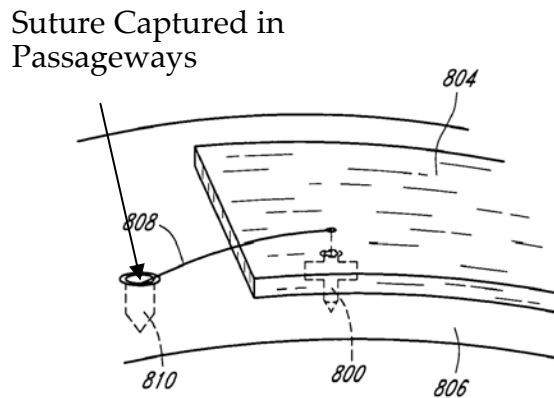


Fig. 16F

This description is also consistent with the provisional applications dated June 2, 2004 and September 17, 2004, both of which include pages from KFx's inventor lab notebooks. The suture capturing anchor is described as a two piece anchor in which the base is inserted into the bone, then the cap is inserted into the base to capture the suture in between the two anchor portions. DDX 114 at KFX0002033-45; KFX0002050-57; KFX0002063-65; DDX 115 at KFX0002116-19; KFX0002127-28; KFX0002133-42).

A suture capturing anchor described in the June 2, 2004 provisional application is shown below in Figure A. Although there is no disclosure in this provisional application of a suture bridge as claimed in the KFx Patents, it does disclose a suture capturing anchor that captures suture by clamping it between an anchor base and an anchor cap. The text accompanying the figure in the lab notebook describes that "the castlations act to prevent the suture from slipping off the lower clam shell's inner boss, thus ensuring that the suture is clamped four times instead of two." KFX0002039. Thus, the suture is attached to the anchor itself.

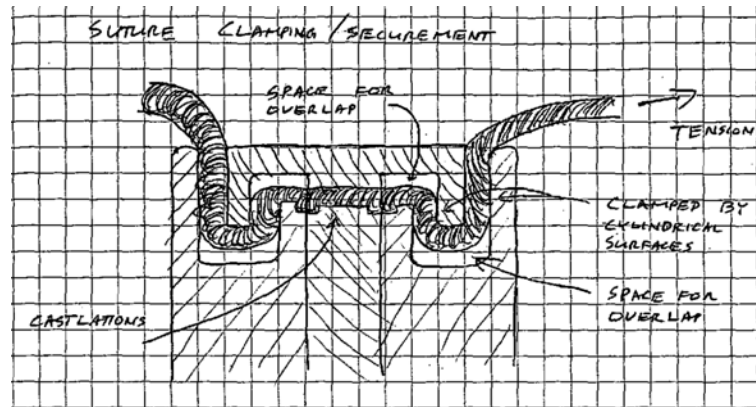


Figure A

Another example from KFx's provisional application (inventor lab notebooks) is shown below in Figure B. This is another two piece anchor in which the suture is captured between the two portions of the anchor. The cap includes a "wavy geometry" and the base includes a "castle geometry" to keep the suture near the post while the anchor cap is being inserted to capture the suture. KFX0002052. This is another example in which the suture is attached to the anchor itself.

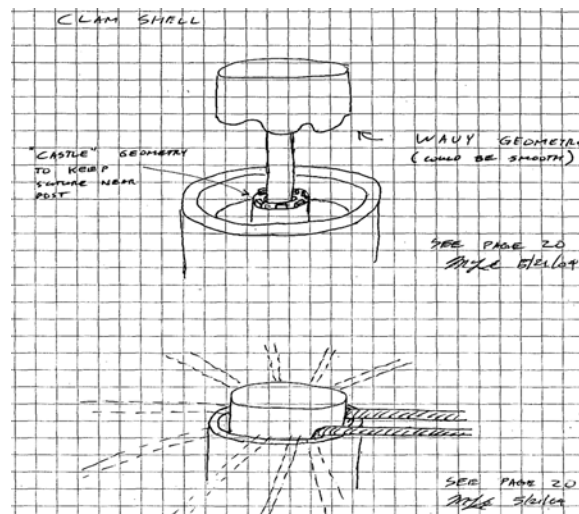


Figure B

Yet another example from KFx's provisional application (inventor lab notebooks) is shown below in Figure C. This is another two piece anchor called a "gridlock" anchor in which the suture is captured in between the two portions of the anchor. Side views and top views are shown in which the anchor base has threads for being screwed into bone. The suture is again located in between the anchor base and the anchor cap. Then the cap is secured into the base to lock the suture in place between the two anchor portions, thereby attaching the suture to the anchor. KFX0002065.

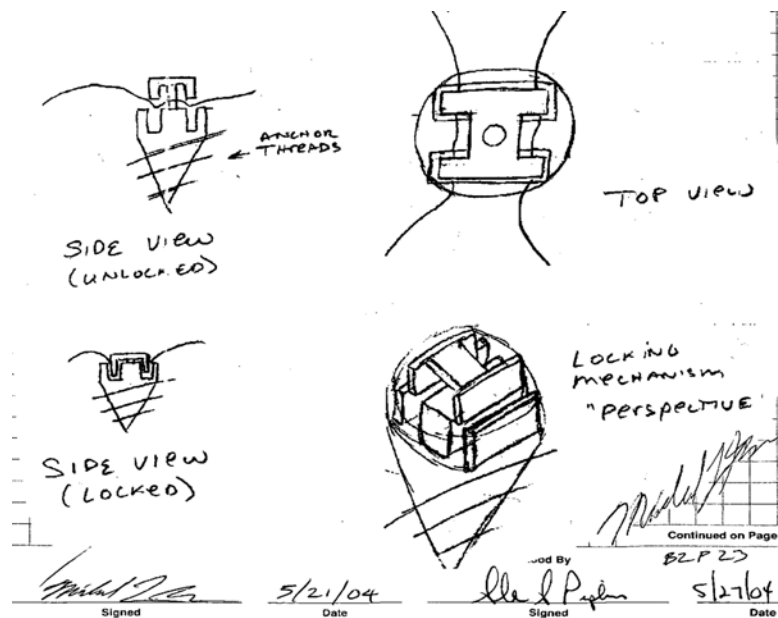


Figure C

C. Prosecution of the KFx Patents

I have also reviewed the prosecution history of the KFx Patents and understand that in response to a rejection based on U.S. Patent No. 5,891,168 to Thal ("Thal '168"), the applicants distinguished their invention by stating that unlike Thal '168, their invention does not secure suture to the second anchor simultaneously with insertion of the anchor into bone. DDX 103 at KFX0001944. The applicants stated that in their invention, the suture is fixedly secured to the

second anchor after its insertion into bone. DDX 103 at KFX0001944. The applicants were able to overcome the rejection based on these arguments made to the Examiner during prosecution.

VII. TESTING AND DEMONSTRATIONS CONDUCTED

I conducted two tests. A first test was to confirm whether Arthrex's accused anchors could be passed through the soft tissue. A second test was to confirm whether the eyelet portion of the accused devices performs any anchoring function.

A. Inserting Corkscrew and SwiveLock Anchors Through Tissue

As explained below, it is my opinion that the KFx Patents require the first anchor to be inserted through the tissue and into bone underneath the tissue and that the accused methods do not infringe because the first anchor is inserted directly into the bone and not through the tissue. *Infra* at 16-23. It is my opinion that the accused anchors are too large to be inserted through the tissue. *Infra* at 22-23.

To confirm whether the accused anchors are too large to be inserted through the tissue, I implanted a two-anchor SutureBridge (medial 5.5mm BioCorkscrew and lateral 4.5mm BioPushLock) and two, two-anchor SpeedBridge (medial 5.5mm SwiveLock and lateral 5.5mm SwiveLock; one with FiberWire and one with FiberTape) into respective Alex shoulder models. A strap of leather was used on the models as the simulated rotator cuff. Rather than removing the cuff, as Arthrex instructs, I inserted the medial anchors through the simulated cuff and into the shoulder model underneath the cuff.

By passing the medial anchor through the cuff, a hole was created through the cuff that was much too large, and unacceptable, for a live patient. This test demonstrates that Arthrex's medial anchors are not intended to be inserted through the soft tissue since they are too large. This is contrasted with the medial anchors described in the KFx Patents, which are designed to

be inserted through the soft tissue. Photographs of the constructs I created are attached as Ex. 2 (ARTH_1257743-58).

B. Eyelet Is Not Part of the Anchor

As described below, it is my opinion that the eyelet on the end of the PushLock and SwiveLock devices are not part of the anchors. Infra at 24-36. One of the reasons for my opinion is that the eyelet does not anchor anything. It does not anchor itself into bone, nor does it anchor the suture to the bone. I demonstrated this by drilling a hole for a 4.5mm PushLock anchor into an Alex shoulder model. I then threaded a strand of suture and threaded it through the eyelet and demonstrated how the eyelet is easily placed into the hole and can be easily removed. I repeated this step several times to show that the eyelet is not being anchored into bone.

I then placed the eyelet at the bottom of the hole and slid the strand of suture through the eyelet back and forth, demonstrating that the eyelet is also not performing any anchoring function with regard to the suture. I then inserted the PushLock anchor body into the bone hole. Only after inserting the anchor body were both the anchor body and the suture anchored in the bone hole. The video of this demonstration is attached as Ex. 3 (ARTH_1257742, ARTH_1257759-61).

VIII. OPINIONS

A. Legal Standards for Patent Infringement

I understand that an accused method infringes a patent claim if the accused method includes every limitation of the asserted claim. I also understand that the accused method may infringe the claim either literally or under the doctrine of equivalents. To infringe literally, the accused method must include every limitation of the claims. Even if the accused method does

not include every limitation literally, there may still be infringement under the doctrine of equivalents if the accused method includes a step that is equivalent to the claim limitation. I also understand that one way to determine whether an accused method step is equivalent to a claimed method step is to determine whether the accused step accomplishes substantially the same function as the claimed step, in substantially the same way as the claimed step and obtains substantially the same result as the claimed step.²

I have reviewed the Court's claim constructions and have applied those constructions in my opinions. Where the Court did not construe a claim term, I have attributed to that claim term what I believe to be the plain and ordinary meaning as it would have been understood by a person of ordinary skill in the art in the 2004 timeframe.

a. Direct Infringement

I also understand that a claim may be infringed either directly or indirectly. A method claim may be infringed directly only by the person performing the steps in the method. A party who does not perform all of the steps (or any of the steps) in a method claim may still be liable

² Dr. Ticker makes only a passing reference to the doctrine of equivalents in his report (Ticker Rep. at ¶ 32) and does not include an analysis for any specific limitations. Dr. Ticker states as a possible excuse for this omission that "Arthrex has not provided a detailed explanation of the basis for its contentions that the Accused Products did not infringe the asserted claims of the '311, '942 and '969 patents." Ticker Rep. at ¶ 180. This is not correct, however, as evidenced by Dr. Ticker's including a section in his report titled "Arthrex's Non-infringement Contentions" and his dedicating a large portion of his report (more than 25%) specifically responding to Arthrex's non-infringement defenses in great detail. Ticker Rep. at ¶¶ 35-83. Dr. Ticker was able to respond in such detail because Arthrex's non-infringement positions had been so clearly set forth in its answers to interrogatories. In any event, Dr. Ticker does not appear to have any specific opinions regarding infringement under the doctrine of equivalents. In the event the Court were to allow Dr. Ticker to amend his report to include such opinions, I reserve the right to further amend my report to respond to those opinions. My opinions regarding no literal infringement are included below. For those same reasons, I do not believe there is any infringement under the doctrine of equivalents because the differences between the accused methods and the missing claim limitations are not insubstantial, and the accused method steps do not accomplish substantially the same functions in substantially the same way and do not arrive at substantially the same results.

for indirect infringement if the party induces another to infringe, or if the party contributes to another's infringement. In this case, I understand that surgeons who perform the accused surgical methods are the accused direct infringers and Arthrex is an accused indirect infringer.

b. Indirect Infringement

1. Inducement

I understand that a party can be liable for inducing another's infringement if: i) there is a direct infringement; ii) the party took action intending to cause the infringing acts; and iii) the party was aware of the patent and knew that the acts, if taken, would constitute patent infringement, or the party believed there was a high probability that the acts, if taken, would constitute patent infringement but deliberately avoided confirming that belief. I also understand that Dr. Ticker does not use this "knew of, or was willfully blind to, the infringement" standard in his opinion. Ticker Rep. at 37. Rather, Dr. Ticker used another standard requiring that Arthrex "knew or should have known that its actions would lead to actual infringement." Ticker Rep. at 37 and 41-42.

2. Contributory Infringement

I further understand that a party who does not directly infringe may nonetheless be liable for contributory infringement if that party: i) sells an apparatus for use in a patented process; ii) the apparatus is not a staple article or commodity of commerce suitable for substantial, non-infringing use; iii) the apparatus constitutes a material part of the invention; iv) the party is aware of the patent and knows that the method may be covered by a claim of the patent; and v) use of the apparatus directly infringes the patent.

3. Opinions of Counsel

I also understand that if a party obtained and reasonably relied upon a competent opinion from counsel regarding non-infringement and/or invalidity of a patent, it is supportive of the fact that the party did not intend infringement nor had a subjective belief that there was a high probability that surgeons were infringing the patent.

B. Use of the Accused Methods Does Not Directly Infringe any Asserted Claims

1. Arthrex's accused methods do not include inserting a first anchor into bone through the soft tissue

Every asserted claim of the '311 Patent includes the step of "inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue." Every asserted claim of the '942 and the '969 Patents includes the step of "inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue." The plain and ordinary meaning of these limitations are that the first anchor is inserted through the soft tissue because the KFx Patents disclose only one method of inserting the first anchor into bone and that is by going through the soft tissue, and it is the only method that KFx invented. Supra at 4-7.

The September 17, 2004 provisional application confirms that inserting the first anchor through the soft tissue was the only method conceived of by the inventors. Supra at 6-7. The application includes pages from the inventor lab notebooks which KFx relied upon as conception documents for its invention. Plaintiff's Preliminary Infringement Contentions, Dec. 1, 2011 at 5; Plaintiff's Preliminary Infringement Contentions as to Newly Asserted Patent Nos. 8,100,942 and 8,109,969, Apr. 9, 2012 at 5. And as described above, the patent specification explains that the first anchor is specifically designed (with a sharp tip) to have a small enough diameter to allow easy passage through the soft tissue without damaging the tissue. Nowhere in the KFx

Patents is there any teaching of removing the soft tissue to insert the first anchor directly into the bone.

KFx's documents confirm this. KFx believed that going through the soft tissue on the medial side was an advantage over the competition, including Arthrex's accused SpeedBridge method. DDX 4 (KFx CEO, Tate Scott, explaining to a surgeon that "one of our advantages [over Arthrex] is a trans-tendon approach"); DDX 5 (explaining that trans-tendon fixation "keeps the medial point of fixation on the cuff in-line with fixation point of the bone anchor, as opposed to placing anchors, retrograding sutures arbitrarily into the cuff and tying a knot"); DDX 6 at KFX0004210 (explaining the advantages of KFx's method over competing methods which require removal of healthy tissue and inserting the medial anchors directly into bone, stating "competing products are either too large in size to pass through the tendon or too small to be an effective anchor" and that "the distinct, time saving procedural approach . . . enables the surgeons to achieve trans-tendon fixation thereby avoiding the tear to repair step and removal of healthy tissue. No other system allows a surgeon to place a medial anchor with the clinically required strength through an intact tendon without having to first complete the tear to then repair").

Michael Green, one of KFx's inventors, testified that although the inventors considered removing the tissue, they chose not to go in that direction because "we thought it was a good idea to do, go through the tendon. We also looked at whether you could go under the tendon [but] that seemed like it would be – have an additional set of challenges." He also explained that "we thought it would be easier to go through if it was simpler." Michael Green Depo. Tr. (Dec. 12, 2012) at 64-65. When Mr. Green was asked again why he intended for the first anchor to go

through the tissue, he testified “I believe it’s easier for the physician to go through it.” Michael Green Depo. Tr. (Dec. 12, 2012) at 231-32.

Similarly, another inventor, Dr. Joseph Tauro, when asked whether he recalled anything specific about the medial anchor in the KFx Patents, testified that “the concept was just so that it could go through soft tissue, that it would be low profile, that, you know, it be small.” Joseph Tauro, M.D. Depo. Tr. (Dec. 15, 2012) at 76-77. When asked why he wanted the medial anchor to go through the soft tissue, Dr. Tauro testified “it gives you the advantage of not -- potentially not having to pass sutures independently.” Joseph Tauro, M.D. Depo. Tr. (Dec. 15, 2012) at 76-77.

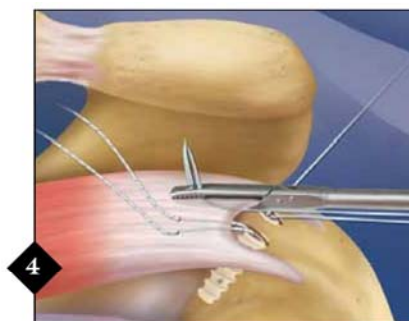
Unlike the claims of the KFx Patents, Arthrex’s surgical techniques for the accused methods instruct surgeons to remove the soft tissue and insert the first anchor directly into bone, then to pass the sutures through the soft tissue.

SutureBridge

For example, the relevant portion of Arthrex’s most recent surgical technique for SutureBridge is shown below. The tissue is removed, then the first anchor (a BioComposite Corkscrew FT) is inserted directly into bone. See Figure 3 below. Next, the suture attached to the Corkscrew anchors are passed through the soft tissue. ARTH_0029220-225. Every prior version of the SutureBridge surgical technique (since the first technique guide was published in 2006) describes this same method of inserting the first anchor. ARTH_0029196-201; ARTH_0029202-207; ARTH_0029208-213; ARTH_0029214-219.



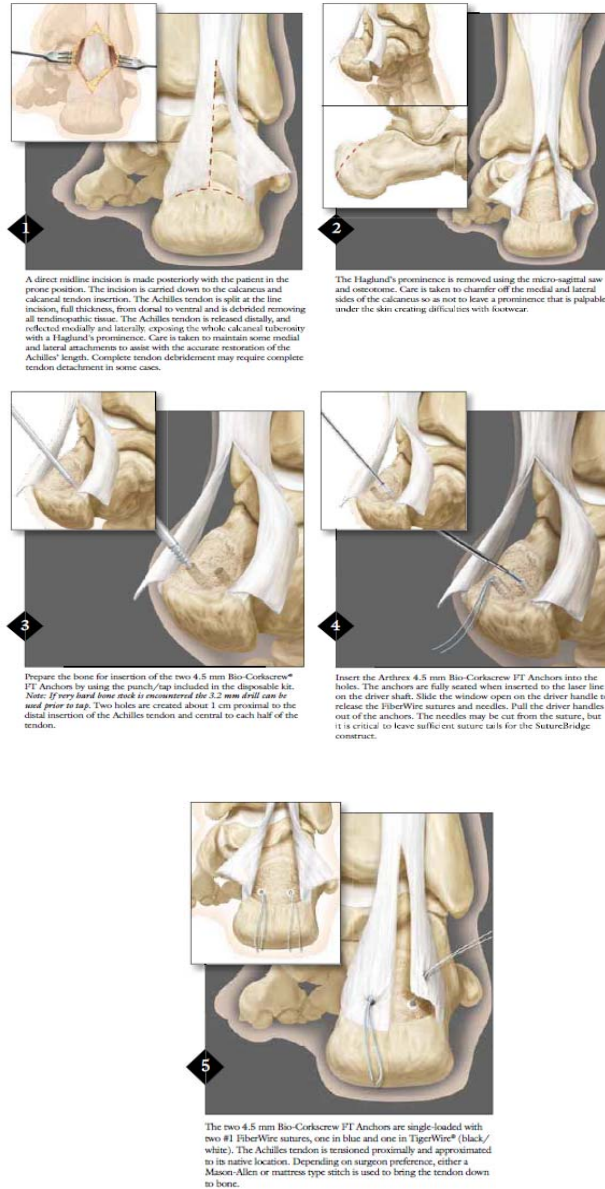
3 Place both BioComposite Corkscrew FT anchors. These anchors will assure full contact of the detached tendon along the medial footprint of the greater tuberosity.



4 Remove one strand of suture from each anchor (preferably opposite colors). Using a KingFisher, retrieve one of the four remaining sutures through the lateral (or anterolateral) cannula and pass it through the tendon using the Scorpion™ Suture Passer. Repeat for the three remaining sutures to create a horizontal mattress configuration. Maintain a soft tissue bridge of one to two centimeters between the mattress stitches.

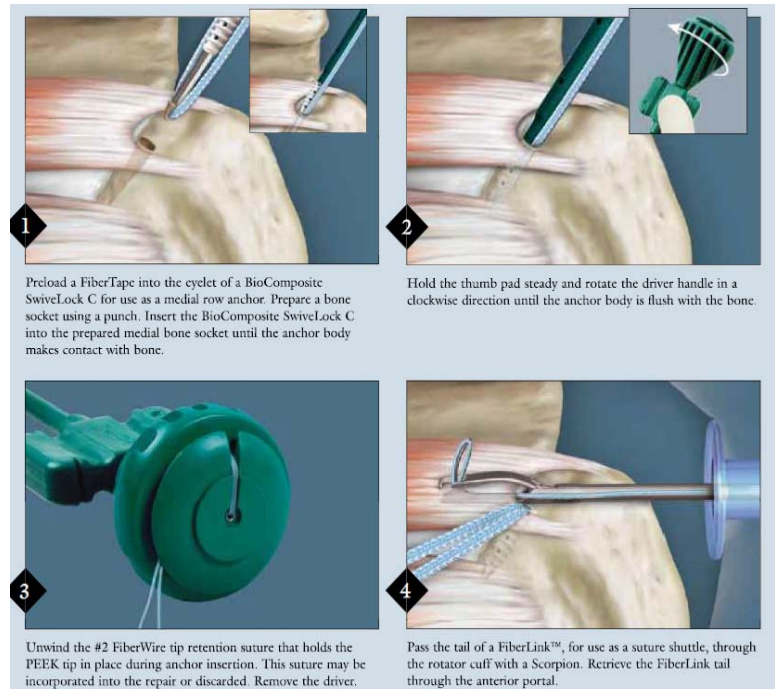
Achilles SutureBridge

Similarly, Arthrex's Achilles SutureBridge surgical technique always instructs the surgeon to split the Achilles tendon to allow for the first anchors to be inserted directly into the bone, then to pass the sutures through the tendon. Referring to caption 1 from the latest Achilles SutureBridge surgical technique (ARTH_0029084-89), shown below, the surgeon is instructed to make a direct midline incision posteriorly. Then the Achilles tendon is split at the line of incision to expose the whole calcaneal tuberosity with a Haglund's prominence. Below at caption 1. The surgeon is then instructed to remove the Haglund's prominence and to prepare the bone for insertion of the two 4.5mm Bio-Corkscrew FT anchors. Below at caption 3. The Corkscrew anchors are inserted until fully seated in caption 4, and the attached sutures are passed through the tissue in caption 5. Every prior version of Arthrex's Achilles SutureBridge surgical technique guides (since the first technique guide was published in 2007) teaches these same steps. ARTH_0029066-71; ARTH_0029072-77; ARTH_0029078-83; ARTH_0219229-234.



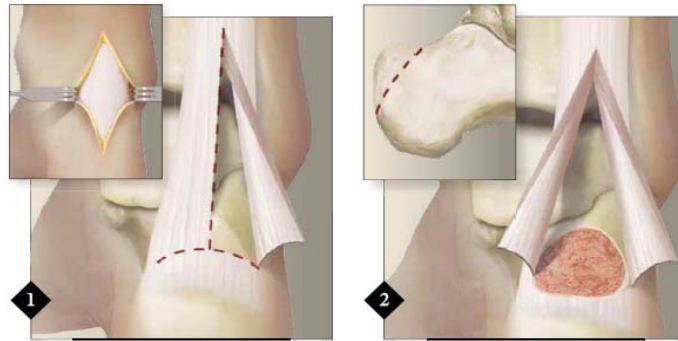
SpeedBridge

Just as with SutureBridge, Arthrex's SpeedBridge surgical technique always instructs the surgeon to remove the soft tissue, insert the first anchor directly into the bone and then pass the attached FiberTape through the soft tissue. See captions 1-4, below, from the latest SpeedBridge surgical technique (ARTH_0029188-95). Every prior version of the SpeedBridge technique guide (since the first one was published in 2008) also teaches these same steps of inserting the first anchor. ARTH_0029164-71; ARTH_0029172-79; ARTH_0029180-87.



Achilles SpeedBridge

Arthrex's Achilles SpeedBridge surgical technique also always instructs the surgeon to remove the soft tissue, insert the first anchor directly into the bone and then pass the attached FiberTape through the soft tissue. See captions 1-6, below, from the Achilles SpeedBridge surgical technique (ARTH_0029060-65).



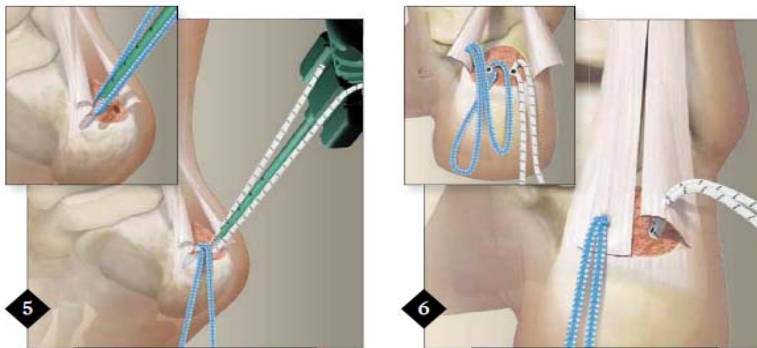
1
A direct midline incision is made posteriorly with the patient in the prone position. The incision is carried down to the calcaneus and calcaneal tendon insertion. The Achilles tendon is split at the line incision, full thickness, from posterior to anterior and is debrided removing all tendinopathic tissue. The Achilles tendon is released distally, and reflected medially and laterally, exposing the whole calcaneal tuberosity with a Haglund's prominence. Care is taken to maintain some medial and lateral attachments to assist with the accurate restoration of the Achilles' length. Complete tendon debridement may require complete tendon detachment in some cases.

2
The Haglund's prominence is removed using the micro-sagittal saw and osteotome. Care is taken to chamfer off the medial and lateral sides of the calcaneus so as not to leave a prominence is palpable under the skin, creating difficulties with footwear.



3
Prepare the bone for insertion of the two 4.75 mm BioComposite SwivelLocks® by drilling down to the laser line or to the shoulder stop when using the drill guide. Two holes are created about 1 cm proximal to the distal insertion of the Achilles tendon and central to each half of the tendon.

4
The punch/tap included in the disposable kit is used to prepare the holes for the SwivelLocks.



5
The two 4.75 mm BioComposite SwivelLocks loaded with FiberTape®, one blue and one white/black, are inserted in the proximal holes. The eyelet should be placed completely in the drill hole until the anchor body makes contact with the bone. Hold the thumb pad steady and rotate the driver handle in a clockwise direction until the anchor body is flush with the bone.

6
Pass the needle attached to the FiberTape through the Achilles tendon on each side.

The medial anchors recommended for use in the accused methods are too large to be inserted through the soft tissue. The medial anchors are anywhere from 4.5mm to 5.5mm in diameter and would create too large a hole and too much damage passing through the tissue. Thus, not only does Arthrex not teach passing the medial anchors through the soft tissue, but it is

my opinion that a surgeon would also not disregard Arthrex's surgical techniques and do so on his own. I have also not seen any evidence that surgeons do so, nor does KFx or Dr. Ticker allege they are doing so. To the contrary, Dr. Ticker agrees Arthrex's anchor do not pass through the tissue. Ticker Rep. at ¶ 79.

My opinion is further supported by a test I conducted in which I inserted either a 5.5mm Bio-Corkscrew anchor or a 5.5mm SwiveLock anchor on the medial side and 5.5mm SwiveLocks on the lateral side of three suture bridge constructs I prepared. I used an Alex shoulder model and a leather strap to simulate tissue. I used FiberWire suture on the first bridge with PushLock. I used FiberWire on one bridge with SwiveLock and FiberTape on another bridge with SwiveLock. I inserted the medial anchors through the simulated tissue and examined the resulting damage to the tissue. Photos of the damaged simulated tissue is shown in Ex. 2, attached to my report.

As can be seen, the anchors created holes through the simulated tissue approximately 4-5mm in diameter. This is clinically unacceptable because of the loss of integrity of the collagen matrix of the tissue. The insertion itself would cause a potentially significant rent in the rotator cuff tissue by virtue of the fact that the anchor tips and the eyelets are blunt and not able to efficiently pierce the tissue, thereby causing untenable damage to the collagen matrix of the rotator cuff tissue. Attempting to place the anchor through the tissue and the into the bone hole would also be disadvantageous in that it would not allow for appropriate tensioning of the sutures or tensioning of the cuff to the greater tuberosity as the hole would be much greater than the suture diameter.

2. Arthrex's accused methods do not include the step of tensioning the suture and fixedly securing the suture *after* inserting a second anchor/distal member of a second anchor/at least a portion of a second anchor into bone

The second anchor/distal member of a second anchor/at least a portion of a second anchor ("second anchor" for simplicity) in the claims of the KFx Patents is the lateral anchor that is not underneath the soft tissue. Each asserted claim of the KFx Patents requires that the first length of suture (attached to the first, medial, anchor) be tensioned to compress tissue to bone and be fixedly secured to the second anchor (or at the second anchor position) only *after* the second anchor/distal member of a second anchor/at least a portion of a second anchor ("second anchor" for simplicity) is inserted into the bone.³ Dr. Ticker and I agree on this order and it is not disputed. Ticker Rep. at ¶ 19. Where we appear to disagree is whether the eyelet of the accused PushLock and SwiveLock devices is part of the anchor itself. For the reasons described below, I do not believe it is part of the anchor, but rather one of several other important but separate parts of the accused device that assist the anchor body with being anchored in the bone and anchoring the suture between the anchor body and the bone wall.

- a. The eyelet is not part of the anchor

The only portion of Arthrex's accused devices that Dr. Ticker claims to be inserted into the bone prior to suture tensioning and prior to wedging the suture between the anchor body and the bone is the eyelet at the end of the driver. Ticker Rep. at ¶¶ 36-76 and Exhibits C-E.

³ I understand that the asserted claims of the '311 Patent include the step of "inserting a second anchor into bone," the claims of the '942 Patent include the step of "inserting a distal member of second anchor into bone" and the claims of the '969 Patent include the step of "inserting at least a portion of a second anchor into bone." Just as Dr. Ticker does (Ticker Rep. at ¶ 36), I address all three limitations together.

I am very familiar with the accused anchors and use them all regularly in my practice. The eyelet on the accused devices is made of either hard plastic, or titanium, in the case of PushLock and SwiveLock, or suture material, in the case of the Bio-Tenodesis screw. The purpose of the eyelet on all of the accused devices is the same; to position the suture at the bottom of the bone hole prior to the anchor body being inserted into the hole. The eyelet does not perform any anchoring function; only the anchor body does that once it is inserted. After the anchor body is inserted into the hole, the anchor body itself is anchored into the bone.

For these same reasons, the eyelet also does not meet Dr. Ticker's medical dictionary definition of an "anchor" as "any device that fixes the position of an object with respect to its surroundings." Ticker Rep. at ¶ 55. The eyelet is not fixed relative to the bone when it is inserted into the bone hole. Only the anchor body has a fixed position when inserted into the bone. Thus, it is my opinion that the eyelet is not part of the anchor and that, as a result, the suture is not tensioned nor is it fixedly secured to the second anchor *after* the second anchor is inserted into the bone, as required by the claims, when only the eyelet has been inserted into the hole.

b. Testing conducted confirms the eyelet does not anchor suture

I conducted testing that confirmed my understanding, based on my personal experience with using the accused products, that the eyelet does not perform an anchoring function. I threaded a strand of suture through an eyelet of the accused PushLock device, inserted the eyelet at the bottom of the hole and was able to pull the eyelet back out of the hole. I repeated this step several times demonstrating that the eyelet was not fixed relative to the bone per Dr. Ticker's dictionary definition. This told me that the eyelet was not being anchored in the bone hole and not performing an anchoring function.

I then placed the eyelet at the bottom of the bone hole and slid the suture back and forth through the eyelet. The suture moved freely demonstrating that the eyelet is not performing any anchoring function with regard to the suture. Then, with the eyelet at the bottom of the hole, I inserted the anchor body into the bone hole which anchored the anchor body to the bone and also wedged the suture between the anchor body and the bone wall. After doing this, neither the anchor body nor the suture moved. A video of my test is attached to my report as Ex. 3. This confirmed that although the eyelet, as well as several other components of the PushLock device, assisted with the placement of the suture at the bottom of the hole, the eyelet does not perform an anchoring function. The only component of the PushLock device that actually performs an anchoring function is the anchor body.

c. Response to Dr. Ticker's report

Dr. Ticker does not appear to contend that the eyelet is actually anchored to the bone. Rather, his opinion appears to be that the eyelet is sometimes referred to as being part of the anchor (Ticker Rep. at ¶¶ 37-54) and that the eyelet performs an important function for positioning the suture relative to the anchor body before the anchor body becomes anchored to bone. Ticker Rep. at ¶¶ 55-61. But Dr. Ticker misses the point. The relevant question is what performs the anchoring function. The answer is the anchor body and nothing more and, importantly, Dr. Ticker does not appear to dispute this.

i. The eyelet is sometimes referred to as part of the anchor

Dr. Ticker cites to several instances where the eyelet is referred to, either by himself, or others, as being part of the anchor. Ticker Rep. at ¶¶ 37-54. Even if Dr. Ticker's citations are accurate, which, as explained below, many of them are not, this merely puts form over substance. The fact that sometimes the eyelet is referred to as being part of the anchor as a colloquial way of

referring to the eyelet in no way impacts whether the eyelet is part of the claimed “anchor” and whether the eyelet is actually anchored, which are the relevant questions. After all, the eyelet is implanted into the body together with the anchor, so it is not surprising that, in a shorthand way, the eyelet is sometimes referred to as part of the anchor. None of the instances to which Dr. Ticker points states that the eyelet is anchored to bone. That is because, as explained above, it does not.

And there are just as many instances, if not more, where the anchor body and eyelet are clearly identified as being two separate pieces and/or as having two very different functions. See, e.g., ARTH_0662528-63508 at ARTH_0662994 (“Missing peek anchor when opened. Eyelet present but anchor was not.”); ARTH_0668798-852 at ARTH_0668829 (“Eyelet and suture pulled thru anchor”); ARTH_1192190 (including several statements indicating that the eyelet is not part of the anchor, for example, “Peek anchor w/peek eyelet,” “Peek anchor w/metal eyelet,” “There was a peek eyelet but no anchor,” “The eyelet and anchor remained intact,” “The eyelet and anchor were off the driver in the sterile packaging,” and “The anchor and eyelet were removed”); ARTH_0945145 (“customer returned driver only, no eyelet, no anchor,” “Eyelet and Anchor left in the bone,” “F[ollow] up with Sandy Harloff (OR Director) indicates the eyelet and anchor were left”); ARTH_0179977-978 (referring to “Pushlock Peek Anchor” and “Pushlock Peek Eyelet” as well as “Swivelock Eyelet” and “Swivelock Anchor,” respectively, as different parts with separate part numbers); ARTH_0060779 (referring to “PushLock Barbed Anchor” and “PushLock Tip Eyelet” as separate parts of the “PushLock™ Sales Demonstration Kit”); ARTH_0681314-1955 at ARTH_0681405 (referring to the “3.5MM PUSHLOCK, EYELET” and “3.5MM PUSHLOCK, ANCHOR” as separate parts with different part numbers); ARTH_0587100-7133 at ARTH_0587126-127 (referring to the “PushLock eyelet” and

“PushLock anchors” as separate entities); ARTH_0097544-570 at ARTH_0097550 (referring to the “3.5 PushLock Eyelet” and “3.5 PushLock Anchor” as separate parts with different part numbers); ARTH_0914707 (referring to the “3.5MM PUSHLOCK, EYELET” and “3.5MM PUSHLOCK, ANCHOR” as separate parts of the same PushLock device with separate part numbers); ARTH_1149298 (referring to the “3.5 PushLock Eyelet” and “3.5 PushLock Anchor” as separate parts with separate part numbers); ARTH_1185718 (listing part numbers separately for anchors and eyelets for 4.5mm PushLock, 2.9mm PushLock and 3.5 PushLock); ARTH_1253554 (listing “PUSHLOCK BARBED ANCHOR” and “BIO-PUSHLOCK TIP EYELET” as separate parts with different part numbers, AR-1926PU-1 and AR-1926PU-2, respectively); ARTH_0897501 (listing “3.5MM PEEK PUSHLOCK ANCHOR” and “PEEK EYELET” as separate parts with different part numbers); ARTH_0103658 (listing the eyelet and anchor as separate parts with different part numbers for 3.5mm and 2.5mm PushLocks); ARTH_1064654 (email from John Sodeika stating that “[t]he driver, eyelet, and anchor minor diameter are the same for both the 4.75 and 5.5” SwiveLock); ARTH_0032395-474 at ARTH_0032415 (memo in design history file referring to “eyelet and anchor” for the SwiveLock); ARTH_0179968-970 (email providing parts needed in PushLock and SwiveLock kits, and listing the eyelets and anchors separately).

Arthrex’s witnesses also testified this way. See e.g., William Benavitz Depo. Tr. (Nov. 28, 2012) at 54:9 (“It’s a one-piece anchor.”), 26:8-12 (Mr. Benavitz denying that the PushLock is a “two-piece anchor” and stating that it is instead a “one-piece anchor”), 26:19-21 (Mr. Benavitz stating that he refers to the PushLock as a “one-piece anchor” “[b]ecause it functions like a one-piece anchor”); William Benavitz Depo. Tr. (Nov. 30, 2012) at 274:4-11 (Mr. Benavitz denying that the PushLock is a “two-part anchor,” stating instead that it is a “one-piece

anchor” and describing that “the anchor” is what actually “fixes the suture to the hole”); Peter Dreyfuss Depo. Tr. (Nov. 29, 2012) at 17:4-15 (Mr. Dreyfuss stating that the eyelet is a “guide for the sutures” that “holds the sutures in place and does not . . . contribute to the holding power or the fixation of the sutures”), 30:2-8 (Mr. Dreyfuss describing a sketch as separately showing “pushing the eyelet to the bottom of the pilot hole” and “inserting the anchor”), 34:2-11 (Mr. Dreyfuss describing how the “3.5 millimeter” PushLock measurement refers to the “anchor” and how the eyelet is not part of the anchor because it “is used for guiding the sutures to the bottom of the hole [and] does not provide any fixation of the sutures”), 36:7-11 (Mr. Dreyfuss stating that “the eyelet [is] distal to the anchor”); Peter Dreyfuss Depo. Tr. (Dec. 5, 2012) at 31:3-11 (Mr. Dreyfuss describing the eyelet and anchor as separate parts); Ashley Willobee Depo. Tr. (Nov. 28, 2012) at 19:18-20:10 (Ms. Willobee stating that the PushLock is not a two-piece anchor because “the eyelet is not part of the anchor” and “the anchor is the part that actually captures the suture”); John Schmieding Depo. Tr. (Dec. 20, 2012) at 173:21 (“The eyelet is not part of the anchor.”); John Sodeika Depo. Tr. (Dec. 3, 2012) at 50:1-51:3 (Mr. Sodeika describing how the “PushLock” has two pieces, “the eyelet and the anchor” and stating that the eyelet is not part of the anchor), 52:2-5 (Mr. Sodeika stating that “the eyelet is not part of the anchor”), 75:11-15 (“The eyelet is at the bottom of the bone socket, and the anchor is at the surface of the pilot hole”), 167:16-168:2 (Mr. Sodeika reading an email that describes the “anchor” and “eyelet” as separate components), 173:9-12 (Mr. Sodeika describing how “the anchor and the eyelet remained in the bone”); Dr. Neal ElAttrache Depo. Tr. (Dec. 7, 2012) at 174:10-17 (Dr. ElAttrache stating that he remembers “anchors breaking,” but does not remember eyelets breaking).

The fact that Dr. Ticker can point to instances where the eyelet is referred to as part of the anchor and I can point to many instances where they are referred to as separate things proves my point. It is not the label that matters; it is what it does, and the eyelet simply does not serve as part of the anchor. Moreover, many of the instances upon which Dr. Ticker relies are not accurately described in his opinion. Dr. Ticker relies upon Dr. ElAttrache saying in a SutureBridge video (ARTH_1253527) that “advance anchor into my pilot hole” is an indication that the eyelet is part of the anchor, but Dr. ElAttrache could be referring to the anchor body and not the eyelet. Moreover, at other points in the video Dr. ElAttrache clearly makes statements indicating that the eyelet is not part of the anchor. See, e.g., ARTH_1253527 at 12:21-31 (referring to “PushLock anchor device . . . made out of bio-absorbable material with PEEK eyelet tip”); 12:31-34 (“thread both stitches through the eyelet”).

The portion of Peter Dreyfuss’s deposition in the Orthopro case relied upon by Dr. Ticker is at best ambiguous, and in another portion of the same transcript Mr. Dreyfuss is clear that the “PushLock” device has two separate components, the “anchor” and the “eyelet.” Peter Dreyfuss Depo. Tr. (Aug. 13, 2009), Orthopro, Inc. v. Arthrex, Inc. (ARTH_1254811-975) at 24:19-25:2 (at ARTH_1254834-835), 137:3-5 (at ARTH_1254947). Dr. Ticker also relies upon page 33 of the PushLock Design History File (ARTH_0032643-33088 at ARTH_0032675), but this page shows that “Bio-PushLock implant (proximal)” and “Bio-PushLock implant (distal)” are two components of the “Bio-PushLock” device, which is the system or device that includes an “anchor.” Indeed, the drawings referenced refer to these two components as “anchor” and “eyelet,” respectively. See, e.g., ARTH_0032643-33088 at ARTH_0032960 (referring to the anchor shown in the drawing on ARTH_0032960 (AR-1926BU-1) as the “barbed anchor” and the drawing shown on ARTH_0032961 (AR-1926BU-2) as the “tip eyelet”).

Dr. Ticker also relies upon page 12 of ARTH_1254978-5061 at ARTH_1254992, which refers to a “2 piece” design that includes a “barbed shaft” and “blunt eyelet.” This page, however, is entitled “PushLock™ vs BioFASTak Suture Anchor,” meaning that the “2 piece” is a reference to the PushLock and not to any “anchor.” Indeed, the only reference to “anchor” on this page is to the “Bio-FASTak Suture Anchor” and that it is a “1 piece: threaded anchor.” Moreover, two pages later the document refers to the “anchor” and “eyelet” as separate pieces. See ARTH_1254992.

In many instances, the eyelet and anchor body are simply described as being part of either the PushLock or SwiveLock devices, but that says nothing about whether the eyelet anchor the suture. See, e.g., John Sodeika Depo. Tr. (Dec. 3, 2012) at 55:13-56:4; ARTH_0032643-33088 at ARTH_0032675 (PDX 43 at 33); ARTH_0037545-548 (PDX 44 at 1); ARTH_0060978-982 (PDX 73 at 4); ARTH_0935448-465 at ARTH_0935454; ARTH_1254978-5061 at ARTH_1254992.

Further, many of the documents relied upon by Dr. Ticker are at best ambiguous regarding the relationship between the anchor and the eyelet. See, e.g., PDX 43 at 376 (ARTH_0032643-33088 at ARTH_0033018); ARTH_1253527; Peter Dreyfuss Depo. Tr. (Aug. 13, 2009), Orthopro, Inc. v. Arthrex, Inc., at 161:22-25 (ARTH_1254811-975 at ARTH_1254971). Dr. Ticker also relies upon cherry picked statements from documents but ignores other statements from those same documents indicating that the eyelet is not part of the anchor. See, e.g., PDX 45 (ARTH_0071120-1190) at ARTH_0071147 (referring to “anchor” and “tip” separately); ARTH_1254978 at 992 (referring to the “anchor” and “eyelet” as separate pieces); William Benavitz Depo. Tr. (Nov. 28, 2012) at 55:10 (just a couple pages before the portion of Mr. Benavitz’s deposition relied upon by Dr. Ticker, Mr. Benavitz makes clear that

the SwiveLock is a “one-piece anchor”); ARTH_0032013-32032 at 2027 (referring to “self-punching eyelets”); PDX 73 (ARTH_0060978-82) (stating at ARTH_0060982 that “driver” (i.e., eyelet) is inserted into the pilot hole and that the “anchor” is subsequently inserted).

With regard to PDX 27 (ARTH_0200545-550), Dr. Ticker states correctly that Mr. Benavitz testified that Arthrex would never promote use of the anchors inconsistent with the instructions. Dr. Ticker, however, failed to also mention that Mr. Benavitz concluded that sentence by noting that the document “certainly is not everything you would need to know to understand how to do [the technique] properly.”

Dr. Ticker relies upon ARTH_0935448-465 for supporting his opinion that PushLock is a “two-component” anchor. Ticker Rep. at ¶ 56. But the quoted portion from page ARTH_0935454 supports my opinion that the eyelet is not part of the “anchor.” For example, the portion of page ARTH_0935454 relied upon by Dr. Ticker states that “[t]he Bio-PushLock consists of two components: an eyelet and an anchor.” This supports my opinion that the PushLock device has two parts, an “eyelet” and an “anchor,” and does not support Dr. Ticker’s opinion that an “anchor” has two parts, one of which is the eyelet. The quoted passage further supports my opinion that the only function performed by the eyelet is to place the suture at the bottom of the hole, and that the suture is not “trapped in the hole” or “locked into place” until the anchor is inserted into the hole.

Dr. Ticker also refers to several documents which recite “self-punching anchor” and concludes that because the metal-pointed portion is the eyelet, the self-punching *anchor* must refer at least in part to the eyelet. Another document, however, refers to “4.75 mm SwiveLock screws with *self-punching eyelets*.” ARTH_0032013-32032 at 2027 (emphasis added).

Following Dr. Ticker's logic, such a quote must certainly indicate that the eyelet is *not* part of the anchor.

- ii. The eyelet contributes to overall anchor function and contributes to fixedly securing the suture

Dr. Ticker also states that the eyelet is part of the anchor because it "contributes to overall anchor function" or that it "contributes to the fixedly securing of suture relative to the implant." Here again, I do not believe Dr. Ticker and I disagree that the eyelet serves an important role, but that is not the question. The question is whether the eyelet itself is actually anchored to the bone. The answer is no.

The problem with Dr. Ticker's approach is that as soon as you identify additional components of the accused devices that "contribute to" anchoring the suture, or to anchoring the anchor body into bone, where do you draw the line? Dr. Ticker arbitrarily draws the line at the anchor body and the eyelet. But under Dr. Ticker's theory, every other component that "contributes to" the anchoring function should also be considered part of the "second anchor" under the claims.

For example, the driver plays a critical role in positioning the suture at the bottom of the bone hole. It also provides a conduit upon which the anchor body travels into the bone hole. The eyelet is also physically attached to the driver until the very last step in the process. Without the driver, the eyelet cannot perform its function of locating the suture at the bottom of the hole and the anchor body cannot be anchored to the bone. Thus, the driver also plays a role in anchoring suture to the bone hole (according to Dr. Ticker's view), yet, Dr. Ticker does not contend that the driver is also part of the anchor.

Another example is the plunger at the back end of the PushLock device or the knob on the SwiveLock device. Both of these components play a role in inserting the anchor body into

the bone. Without each of these, there would be no anchoring function at all. But Dr. Ticker does not contend that the plunger or the knob are part of the anchor.

The point is that while all of these components are part of the accused PushLock and SwiveLock devices (as Dr. Ticker states at ¶ 55), they are not part of the “anchor” portion of those devices. While every component of each accused device is necessary to the overall function of the anchor, and, in that view, “contributes to” that overall function, only the anchor portion is actually anchored to the bone and anchors suture to the bone.

Dr. Ticker also points to three instances of eyelet failure, six years ago, and concludes that the eyelet must be anchoring the suture since when the eyelet failed, the suture was not secured to the bone. Ticker Rep. at ¶ 59. But not a single one of these instances conclude that the only reason the suture came out of the bone is due to the eyelet’s failure. In fact, in my experience, the opposite is true. Eyelets break from time to time as the anchors are inserted into bone, yet instances of sutures becoming loose from the repair are rare. See, e.g., ARTH_0662527. The reason is that the eyelet is not part of the anchoring system.

If Dr. Ticker’s analysis were correct, it would, once again, be true for every other component of the accused devices. If, for example, the inserter were to malfunction during insertion of either the eyelet or the anchor body, then the anchor body would certainly not be securely anchored to the bone. But this does not mean the inserter performs an anchoring function. The same is true for the eyelet. The fact that the suture came out of the bone in a few instances when the eyelet failed does not make the eyelet part of the anchor.

Dr. Ticker also points to an internal test conducted by Arthrex in 2005 on a prototype eyelet that is not part of this case, and which operates in an entirely different manner than the eyelets of the accused devices. Ticker Rep. at ¶ 60. First off, the test is not of a bridged suture

anchor construct such as the constructs at issue in this case. This is reason alone for it to be discounted since the forces acting on the anchors are very different in a bridged construct as compared with inserting an anchor into bone (or simulated bone) and pulling to failure.

Another reason why the test is irrelevant is because the prototype eyelet is not a closed eyelet like those on the accused devices, but rather it is an open eyelet and thus captures suture in an entirely different way. ARTH_0078496. The proximity of the prototype eyelet to the anchor body is also very different than that of the accused devices. For example, the test report proposes a design modification to enable the eyelet to remain within the anchor body during insertion. ARTH_0078496. The eyelet portion on the accused devices, however, does not engage any inner portion of the anchor body. Rather, the eyelets are designed to remain a separate piece inside the bone hole. ARTH_0032643-33088 at ARTH_0032960-61; ARTH_0032475-2642 at ARTH_0032504, 2505.

This test also lacks any relevance to the infringement issues here because it uses a FiberChain suture material which operates in a different manner than the sutures used in the accused methods. FiberChain is a series of chain links made of suture material that are connected together and intended to grasp onto the anchor in a different way as compared with the accused devices using FiberWire or FiberTape. Rather than being threaded through the eyelet, as with the accused devices, FiberChain is captured by a fork on the prototype open eyelet device. The mechanisms and forces acting on such a construct are different and unrelated to the forces acting on the accused constructs. Thus, I do not believe they are relevant to the infringement issues in this case.

Dr. Ticker also points to pull-out test results of a SwiveLock with a self-punching, metal eyelet compared with a SwiveLock with a PEEK eyelet and concludes that the higher pullout

force is due to the eyelet. Ticker Rep. at ¶ 61. Dr. Ticker offers no analysis, nor any basis, for his conclusion. The additional pullout could be due to many different factors including the size of the hole into which the anchor is inserted. The size of the hole is certainly going to be different with a self-punching eyelet versus an anchor in which the hole is pre-drilled or pre-punched. More importantly, even if the higher pullout were due to the size of the hole created by the metal eyelet, this says nothing about whether the eyelet actually performs an anchoring function and Dr. Ticker offers no evidence that it does. For the same reasons described above, I do not believe the eyelet on the accused devices, whether self-punching, or PEEK, performs any anchoring function.

3. Arthrex teaches to tension the suture before the eyelet is placed into the bone hole

I understand that each claim of the KFx Patents requires the first length of suture from the medial anchor be tensioned to compress the tissue to bone only *after* the second anchor is inserted into the bone. Dr. Ticker points to certain instances where the eyelet portion of the accused devices is inserted into the bone and where suture tension is adjusted at that point and states that tensioning of the suture occurs after the anchor is inserted into bone. Ticker Rep. at ¶¶ 36-76 and Exhibits C-E. For the reasons described above, I do not believe the eyelet is part of the accused anchors. If it is determined that the eyelet is not part of the anchor, then the alleged tensioning cannot satisfy this claim limitation because it all occurred before the anchor body is inserted into the bone hole.

But even if Dr. Ticker is correct and the eyelet is part of the anchor, it is my opinion that this claim limitation is not met because Arthrex instructs surgeons to tension the suture *before* the eyelet is placed into the bone hole. If, and only if, the surgeon is not satisfied with the tension at that point, is he instructed to remove the eyelet to readjust suture tension then place the

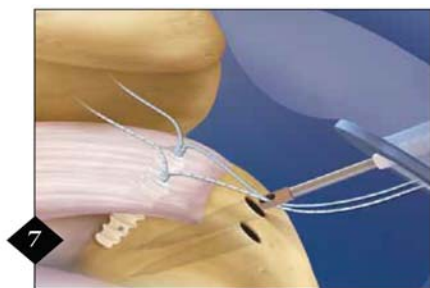
eyelet back into the bone hole. This readjustment, of course, also occurs before reinsertion of the eyelet. Dr. Ticker does not contend (nor could he) that tensioning in these ways infringes the claims of the KFx Patents. Alternatively, instead of removing the eyelet to readjust tension, if tension only needs to be added (and not reduced), the surgeon can leave the eyelet at the bottom of the hole and adjust tension. In his report, Dr. Ticker focuses only on this last alternative (which simply adds tension) and all but ignores the fact that tensioning has already occurred before the eyelet is placed (or replaced) in the hole and that any adjustment of tension occurs only if necessary.

Arthrex's SutureBridge technique guide instructs surgeons to tension the suture to compress the tissue to bone prior to placing the eyelet in the bone hole. ARTH_0029920-25. With reference to Figure 7 from the technique guide, shown below, the surgeon is instructed to bring the eyelet to the edge of the pilot hole while holding onto the suture tails. The guide explains "this will reduce the tendon to its desired position on the footprint." The guide also explains that as a result of this tension being applied, "the knot stack from the medial anchors is tensioned flat against the tendon, minimizing potential impingement issues from the suture." Thus, the guide is clearly instructing that the suture be tensioned because that same tension is forcing the medial knots to lie flat. And that same tension will "reduce the tendon to its desired footprint." This language is important since it describes the "desired footprint," meaning the original tendon footprint.

Dr. Ticker's report states "there is no indication that tension is to be applied, merely that tails are held" and that "the tendon will be reduced to its desired footprint . . . because the sutures are draped over the lateral tendon." Ticker Rep. at ¶ 63. Dr. Ticker is silent, however, regarding the caption underneath Figure 7 describing that the tension applied to the suture forces the

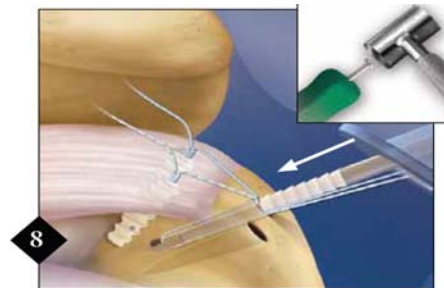
medial knots to lie flat. It is also my opinion that the suture merely being “draped over the lateral tendon,” as Dr. Ticker suggests, would not reduce the tendon to its desired footprint. In fact, I note that Dr. Ticker is very careful on this point, as he only states that the tendon is reduced without “final” tension. Ticker Rep. at ¶ 63. This itself is an admission that tensioning has occurred.

In my opinion, it is clear that what is being described to surgeons is that the suture is tensioned, just as the caption states, and as a result, the medial knots are lying flat and the tendon is reduced to its desired footprint, and that all of this occurs prior to the eyelet being inserted into the bone hole.⁴



Bring the distal tip of the BioComposite PushLock to the edge of the pilot hole while holding onto the suture tails. This will reduce the tendon to its desired position on the footprint.

Note: The knot stack from the medial anchors is tensioned flat against the tendon, minimizing potential impingement issues from the suture.



Completely advance the driver into the pilot hole beyond the first laser line, until the anchor body contacts bone. Evaluate tissue tension. If it is determined that the tension is not adequate, the driver can be backed out and tension readjusted. Alternatively, additional tension may be applied, while leaving the driver in place, by pulling on each suture strand independently.

Use a mallet to tap the anchor body into the pilot hole until the second laser line is flush with the humerus.

⁴ Dr. Ticker states that it would be difficult to properly tension the medial sutures without “stabilizing” the eyelet by inserting it into the bone hole. Ticker Rep. at ¶ 67. I disagree. Since there are two suture strands threaded through the eyelet, there is a fair amount of friction between the sutures and the eyelet. As the surgeon holds onto the loose ends of the sutures and moves the eyelet toward the lateral hole, the sutures will be tensioned to remove any slack and the tissue will be reduced to its desired footprint, just as the technique guide explains. Dr. Ticker’s description of how the tensioning must be achieved is simply inaccurate, nor is it the description in Arthrex’s surgical technique guide. There is no need to “stabilize” the eyelet to tension only after the eyelet is located above the hole. Tensioning occurs as the eyelet is moved toward the lateral hole and by the time the eyelet is over the hole, tensioning is already complete.

Next, with reference to Figure 8, shown above, the guide instructs surgeons to insert the eyelet into the bone hole and to evaluate tissue tension. The guide then states “if it is determined that the tension is not adequate, the driver can be backed out and tension readjusted.” Dr. Ticker’s report is silent about this method of adjusting tension. In my opinion, the guide is clearly instructing surgeons that one way to readjust tension is by removing the entire driver, including the eyelet, from the bone hole, then readjusting tension.

The last option given to surgeons by the guide states, “alternatively, additional tension may be applied, while leaving the driver in place, by pulling on each suture strand independently.”⁵ Dr. Ticker ignores the evidence that “it is very rare” to add tension in this

⁵ Dr. Ticker points to several instances of surgeons exercising this last alternative way of adjusting tension (only after tension has already been applied). Ticker Rep. at ¶¶ 65, 73. It does not surprise me that a few surgeons practice this alternative method since Arthrex does instruct surgeons that this is one possible way to adjust suture tension. It also does not change the fact that tension has already been applied before the eyelet was placed in the hole. Based on the use of these accused methods by myself and my colleagues, my instructing others about how to conduct these surgeries, the Arthrex technique guides described above, and my conversation with Bill Benavitz, Director, Product Management, Shoulder and Elbow at Arthrex, it is my opinion that no more than approximately 10% of surgeons using the accused methods (and probably less) tension the suture with the eyelet in the hole.

Dr. Ticker also mischaracterizes many of the instances upon which he relies. For example, contrary to the assertion made by Dr. Ticker, ARTH_0983195 does not “unequivocally show and instruct tensioning after insertion of the distal eyelet.” In fact, it appears not to show any tensioning at all after insertion of the eyelet. In addition, the “Tibone Video” (KFX0041657) also does not show tensioning after insertion of the eyelet and instead unequivocally teaches tensioning before insertion of the eyelet. With regard to the first PushLock, at 6:26 of the Tibone Video, Dr. Tibone does say “now you’ve got tension on your suture after the eyelet has been inserted into the hole,” but I believe it is more likely that this refers to the tension that Dr. Tibone instructed should be applied prior to insertion of the eyelet at 6:16, and does not instruct that new tension should be applied at this point. With regard to the second anchor, even though Dr. Tibone says that “tension is applied to the suture” after the eyelet is in the hole, the spoken instructions for at least the second anchor do not appear to be in sync with the steps seen in the video. Instead, Dr. Tibone appears to be quickly summarizing the steps for the second anchor while the steps are being quickly performed. Moreover, the suture does not appear to be tensioned after insertion of the eyelet for either the first or second PushLocks in the Tibone Video.

manner. Peter Dreyfuss Depo. Tr. (Dec. 5, 2012) at 158-59. In my opinion, this caption is instructing surgeons that they may be able to *add* tension to the suture (which has already been applied) with the eyelet inside the bone hole. The instruction explicitly says *add* tension; it never says the tension can be reduced (i.e., the suture loosened) with the eyelet in the bone hole and does not instruct surgeons to do so. In my opinion, it would be very difficult to reduce the tension on the suture with the eyelet inside the hole since the frictional forces within the hole will tend to hold the sutures very tightly.⁶ It would be much easier to reduce tension by removing the entire eyelet from the hole and then backing out the suture, just as the guide instructs.⁷

Similarly, the SpeedBridge surgical technique guide instructs surgeons to “adjust tension if necessary” after the eyelet is inserted into the bone hole. ARTH_0029164-71; ARTH_0029172-79; ARTH_0029187.⁸ The same is true for the Achilles SpeedBridge technique

In the “Millett Augmented” video (KFX_0041343) cited by Dr. Ticker, the insertion of at least one of the SwiveLocks does not involve tensioning the suture after insertion of the eyelet. In the “Millett Video” (KFX_0041420) cited by Dr. Ticker, the eyelets in both lateral SwiveLocks are withdrawn at least partially during tensioning. In “Burkhart 1” (KFX_0041409), Dr. Burkhart instructs to “get all the slack out” prior to inserting the eyelet, and tensioning occurs *before* the eyelet is placed at the bottom of the hole. This is also true in “Burkhart 2” (KFX_0041342).

⁶ Dr. Ticker appears to agree when he acknowledges it could be “inconvenient” to diminish suture tension with the eyelet in the bone hole. Ticker Rep. at ¶ 70. He then points to several instances in which the eyelet is placed in the bone hole and tension is added to the suture. Ticker Rep. at ¶ 70. This is what I described above as the last alternative instruction given to surgeons in which suture tension can be *added* (but not easily decreased) when the eyelet is inside the bone hole.

⁷ Dr. Ticker points to a surgical video in which Dr. ElAttrache supposedly reduces suture tension with the eyelet in the bone hole. Ticker Rep. at ¶ 69. That is not what is occurring in the video. Rather, Dr. ElAttrache explains in the video that he is repositioning the tissue. He does not state he is loosening the tissue or suture tension.

⁸ Dr. Ticker states that the current version of the SpeedBridge technique guide instructs surgeons to “adjust tension of each FiberTape limb individually” and that the “if necessary” language was removed because tensioning after the eyelet is inserted is now much more important. Ticker Rep. at ¶ 72 and footnote 2. As I described above, the fact that tension is “adjusted” means it has already occurred before the eyelet is in the bone hole. Dr. Ticker’s

guide (ARTH_0029060-65). It is my opinion that these guides are instructing surgeons that by the time the eyelet is actually placed in the bone hole, suture tension has already been applied to compress the tissue to bone, and only “if necessary,” suture tension could be “adjusted” meaning added, when the eyelet is placed in the hole. This language signals that by this time, the suture has already been tensioned and the tissue has already been reduced to its desired footprint. That is why the surgeon is instructed to “adjust tension.” In my experience with using these products, the vast majority of the time, when tensioning has occurred before the eyelet is in the bone hole, it does not need to be readjusted after the eyelet is placed in the bone hole.⁹

In addition to its technique guides, Arthrex also instructs surgeons to tension the sutures before placing the eyelet in the bone hole through videos, animations, presentations and instructions to the sales force.¹⁰ See, e.g., ARTH_0060779 (instructing the sales force to “[p]osition the tip of the driver over the pre-drilled pilot hole, and tension the suture tails” in

statement also ignores that by the time the latest technique guide was published, the three prior guides already made clear that any such tension adjustment was only “if necessary.” In my opinion, tension adjustment did not become mandatory when the last technique guide was published simply because those two words were not included. To the contrary, by the time the last guide was published, surgeons were already familiar with the operation of SpeedBridge and have been since 2008 when the first guide was published. Thus, surgeons would already know that any adjustment of tension after the eyelet is in the bone hole would be on an as-needed basis only and not mandatory.

⁹ Dr. Ticker points to the last tension adjustment alternative (i.e., to tension the suture with the eyelet still in the hole) in the surgical technique guides and rather than recognizing this is only an alternate instruction to adjust tension after tension has already been applied, he concludes that “removal of the driver is no longer advocated because tensioning after insertion is the recommended technique.” Ticker Rep. at ¶71. This ignores the testimony that tension is typically applied before insertion of the eyelet to the bottom of the hole. And even where tension is adjusted, this ignores the clear language of the technique guide instructing surgeons to remove the driver to readjust tension before it states, as the last option, to tension the suture with the eyelet still in the bone hole.

¹⁰ Dr. Ticker expresses doubt that it is possible to tension the suture prior to the eyelet being inserted into the bone hole. Ticker Rep. at ¶¶ 67-68. As shown below, not only is it possible, but it is the primary method taught by Arthrex and it is commonly done by surgeons.

“Step 3,” and then “[i]nset the driver to the 1st laser line” in “Step 4”); ARTH_0587100-7133 (slides for presentation given by Dr. Cole showing the steps for SutureBridge and showing on page ARTH_0587126 the suture being tensioned prior to insertion of the eyelet and on the next page (ARTH_0587127) showing the eyelet and anchor being inserted without further tensioning); ARTH_0878144 (Dr. Tibone performing a SutureBridge and stating at 7:00 that “tension is applied to the suture” prior to insertion of the eyelet); ARTH_0878182 (Arthrex animation showing that no tension is applied after the eyelet is inserted); ARTH_0878129 and KFX_0041409 (Dr. Burkhart instructing to “get all the slack out” prior to inserting the eyelet; ARTH_0878135 and KFX_0041420 (Dr. Millett at least partially withdrawing the eyelets in both lateral SwiveLocks during tensioning); ARTH_1253525 (Dr. San Giovanni tensioning the suture before inserting the eyelets of both lateral/distal SwiveLocks (at 26:33 and 27:38)); ARTH_1253528 (Dr. Amendola tensioning the suture (at 14:44-15:06 and 15:49) before inserting (at 15:06 and 15:50) the eyelets of both lateral/distal PushLocks); ARTH_0878093 (showing Dr. Brady tensioning (at 4:44) before inserting the eyelet of the lateral PushLock); ARTH_0878106 (showing tensioning (at 2:32 and 3:03) before inserting (at 2:36 and 3:05) the eyelets of the lateral SwiveLocks all the way into the hole); ARTH_0878116 (showing Dr. Burkhart tensioning (at 1:50-1:52) the suture before inserting the eyelet of the SwiveLock); ARTH_0878334 (showing tensioning before inserting eyelet and no tensioning after insertion of eyelet); ARTH_0878235 (Arthrex medical education video showing all tensioning occurring before insertion of the eyelet).

As described above, the KFx Patent claims require that the suture be tensioned to compress tissue to bone only after the second anchor is inserted into bone. Even assuming Dr. Ticker is correct and the eyelet is part of the anchor, for the reasons described above, it is my

opinion that the accused methods do not infringe the KFx Patents because Arthrex teaches surgeons to tension suture before the eyelet is placed into the bone hole.

4. Arthrex's accused methods do not include "fixedly securing the first length of suture to the second anchor (or at the second anchor position)"

I understand that each claim of the KFx Patents includes the step of "fixedly securing the first length of suture to the second anchor" or "at the second anchor position." I understand the Court ordered that this claim limitation be interpreted according to its plain and ordinary meaning. For the reasons described below, it is my opinion that the plain and ordinary meaning of this language, to a person of ordinary skill in the art in the 2004 timeframe, would have been that the suture must be fixedly secured *to the anchor* itself.

There are many different ways to fixedly secure suture to an anchor. Some examples include internal fixation using a suture lasso around the tip and the use of an internal interference or cam mechanism. As described above, the public record, including the specification and provisional applications, disclose precisely how the suture is fixedly secured to the second anchor (or at the second anchor position) – that is to capture the suture within a suture securing mechanism between the two anchor portions. Supra at 6-12. I also understand that in its claim construction Order, the Court included the definition of "fixedly secure" from the specification in its Order; specifically, "that the suture within the securing mechanism cannot be easily moved relative to the bone anchor." Order Construing claims, Oct. 10, 2012 at 4.

The accused anchors wedge the suture between the anchor body and the bone and do not fixedly secure the suture to the second anchor itself and thus, do not meet this limitation. The KFx Patents do not describe the suture as being wedged between the second anchor and the bone. To the contrary, the specification, and provisional applications, are consistent with the

claim language requiring that the suture be secured to the anchor, and describe the suture being captured within the suture securing mechanism within the anchor itself. Supra at 7-12.

The applicants also distinguished their invention over the Thal '168 Patent during prosecution of the '311 Patent. Specifically, they stated their invention does not secure the suture simultaneously with inserting the anchor into bone. Supra at 11-12. Rather, they explained, their invention secures suture to the second anchor only after the second anchor is inserted into bone. Supra at 11-12.

The anchor disclosed in the Thal '168 Patent, just like the accused PushLock and SwiveLock anchors, wedges suture between the anchor body and the bone. DDX 104 at Figure Figure 2. Wedging the suture between the anchor body and the bone wall occurs simultaneously with inserting the anchor body. By distinguishing their invention over Thal '168, the applicants were explaining that they did not intend to cover an anchor that wedges the suture between the anchor body and the bone.

This public record is reason enough for me to believe that a person of ordinary skill in the art, reviewing the patent specification, the provisional applications and the prosecution history would understand that the KFx Patents do not cover a method in which suture is wedged between the second anchor body and the bone.

These same inventors also testified that they did not intend for their invention to cover a lateral (second) anchor that wedges the suture between the anchor body and the bone. One inventor, Michael Green, testified as follows (objections omitted):

Q: Did you ever consider a lateral anchor that secured the suture by compressing it between the bone and the anchor as opposed to between two pieces of the anchor?

A: The answer is yes, *but it was discounted almost immediately.*

Bone is not a reliable geometric shape after you've driven a screw into it. *You couldn't reliably count on it* supplying a clamping force to something because it can -- it can crack. It can change. It can chip. It can do weird things to you. You don't -- you have no control over what it will do. *So you need to clamp it against -- or between two known surfaces with known frictional characteristics and known geometric relationships to one another.* If you take one of those elements away and make it amorphous or unknown, *you'd have no way of knowing what that clamping force would be.* Unless you have a complying clamping force, and then you'd have to worry about another hole. So it's possible. *We considered it briefly. It wasn't pursued.*

Michael Green Depo. Tr. (Dec. 12, 2012) at 216-17 (emphasis added). Mr. Green “discounted almost immediately” the idea of wedging suture between the anchor and the bone and believed it would be better to secure the suture to the anchor itself by, in this particular instance, clamping the suture “between two known surfaces with known frictional characteristic and known geometric relationships to one another.” This testimony is consistent with the claim language requiring that the suture be secured to the anchor itself, as well as the specification and the provisional application disclosing a specific way of securing the suture to the anchor itself.

Another inventor, Dr. Tauro, testified very similarly in explaining why he never considered a lateral anchor that wedges suture between the anchor and the bone:

Q: Did you ever consider any lateral anchor *where the suture is wedged between the anchor and the bone?*

A: *No.*

Q: Why?

A: In the rotator cuff application, It's been my opinion that that's -- *the bone is*

too soft up there to rely on it as part of the fixation of the suture.

Q: So this configuration – I’m sorry, this design in figure 6-B provides better fixation of the suture?

A: In my opinion. Here you have an actual positive metal on metal locking mechanism. If you use something that wedges a suture between the anchor and bone, *you have to depend on the bone being strong, which is often not the case.*

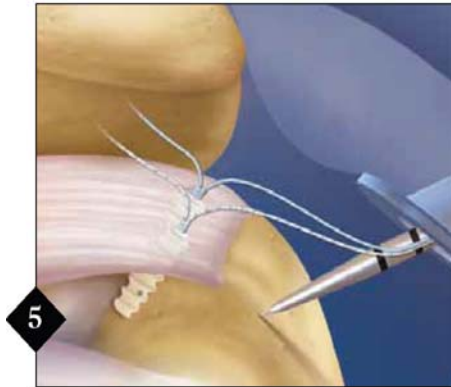
Joseph Tauro, M.D. Depo. Tr. (Dec. 15, 2012) at 94-95 (emphasis added). Thus, two of KFx’s inventors (and both inventors of the ‘311 and ‘942 Patents) did not consider wedging the suture between the anchor body and the bone. Instead they opted to secure the suture to the second anchor, and specifically, via the “metal on metal locking mechanism” described in the specification and provisional applications. KFx also internally described Arthrex’s method of wedging suture between the lateral anchor and the bone as a “weakness.” DDX 9 at KFX0031445.

5. Arthrex’s SutureBridge and Achilles SutureBridge methods do not include the step of fixedly securing suture to the second anchor (or at the second anchor position) without tying any knots

Every asserted claim of the KFx Patents require “fixedly securing the first length of suture to the second anchor (or at the second anchor position) without tying any knots.” I understand the Court interpreted this to mean “the first length of suture cannot be easily moved relative to the second anchor and that this step is completed without tying any knots.”

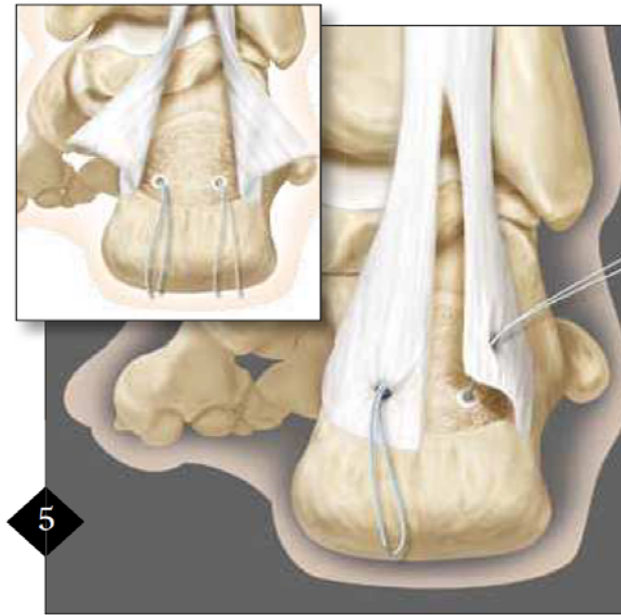
Arthrex’s SutureBridge method requires that knots be tied over the medial anchors. This is described below in the caption under Figure 5 from the technique guide. ARTH_0029920-25. Every prior version of the SutureBridge technique guide includes this same instruction dating

back to 2006. ARTH_0029196-201; ARTH_0029202-207; ARTH_0029208-213;
ARTH_0029214-219.



Tie the medial row but do not cut the FiberWire® tails. These tails will be draped over the lateral aspect of the tendon and held in place with two knotless PushLock anchors.

The Achilles SutureBridge technique guide also instructs surgeons to tie a knot over the medial anchors, as shown below in Figure 5 of the latest guide. ARTH_0029084-89. The same instruction is included in each prior version of the Achilles SutureBridge guide dating back to 2007. ARTH_0029066-71; ARTH_0029072-77; ARTH_0029078-83; ARTH_0219229-234.



The two 4.5 mm Bio-Corkscrew FT Anchors are single-loaded with two #1 FiberWire sutures, one in blue and one in TigerWire® (black/white). The Achilles tendon is tensioned proximally and approximated to its native location. Depending on surgeon preference, either a Mason-Allen or mattress type stitch is used to bring the tendon down to bone.

I understand from speaking with Bill Benavitz, Arthrex's Upper Extremity Product Manager, that the reason for the medial knots is to prevent slippage of the FiberWire suture wedged between the lateral PushLock anchors and the bone. This is also supported by a test conducted by Arthrex in 2005 showing that the suture slippage is greatly reduced, and the strength of the construct is greatly increased by adding medial knots to the construct.

ARTH_0987623-25. Other Arthrex documents also explain that without medial knots, the slippage on SutureBridge was unacceptable. PDX 165; ARTH_0008138-144; ARTH_0008145-152; ARTH_0019924-932 at ARTH_0019928; ARTH_0133728-731; ARTH_0162588-592; ARTH_0179316-324; ARTH_0179325-333; ARTH_0180371-377; ARTH_0186669-673; ARTH_0187436-449; ARTH_0195906-910; ARTH_0987620-25; ARTH_0978713; ARTH_1009218-229; ARTH_1016104. Even if wedging were considered a way to fixedly

secure the suture to the anchor itself (which I do not believe it is), this means the suture is not fixedly secured to the second anchors (or at the second anchor position) without tying any knots, as required by the claim, because knots *are* tied to fixedly secure the suture to the second anchor.

I have also reviewed KFx documents acknowledging that SutureBridge “requires knot tying” and others that refer to this requirement as a “weakness.” DDX 9 at KFX0031445; DDX 5 at KFX0003092.

Dr. Ticker acknowledges that knots are tied over the medial anchors in SutureBridge, but perhaps his opinion is that the claim limitation is met simply because that knot is over the medial (first) anchor not the lateral (second) anchor. Ticker Rep. at ¶ 81. Any such opinion completely misses the point. It is not where the knot is located that matters; it is what it does. Here the record shows that the purpose of the medial knot is to fixedly secure the suture to the lateral anchor (even if wedging were a form of fixedly securing to the lateral anchor).

SutureBridge uses Corkscrew anchors medially and PushLock anchors laterally. As KFx’s inventors acknowledged, bone is unpredictable and wedging the small diameter FiberWire suture between the anchor body and the bone, while sufficiently strong when used with harder bone, may not be sufficient when used with softer bone, as is the case in certain rotator cuff repairs. Michael Green Depo. Tr. (Dec. 12, 2012) at 216-17; Joseph Tauro, M.D. Depo. Tr. (Dec. 15, 2012) at 94-95. I understand that because Arthrex does not know the hardness of the bone in which the anchors are being used, Arthrex recommends always tying medial knots to ensure the FiberWire will never slip past the lateral PushLock anchors. The procedures must be designed for the assumed worst case bone.

Because the claim construction requires that the suture be fixedly secured to the second anchor without tying any knots, and SutureBridge does require knots to fixedly secure the suture

to the second anchor (assuming wedging is fixedly securing to the second anchor), it is my opinion that SutureBridge does not literally infringe any of the asserted claims of the KFx Patents.

C. Arthrex Does Not Indirectly Infringe the KFx Patents¹¹

As described above, I understand that for a party to be liable for indirect infringement, there must be a direct infringement. For the various reasons described above, I do not believe surgeons using the accused methods directly infringe KFx's Patents. Thus, as I understand it, there can be no indirect infringement. But even if surgeons using the accused methods were found to be directly infringing, it is my opinion that Arthrex should not be found to have induced, or contributed to, that direct infringement.

1. Arthrex does not induce infringement

Assuming direct infringement is found, I understand that for Arthrex to be liable for inducing infringement, Arthrex, among other things, must have intended infringement, must have been aware of the KFx Patents and knew that the surgeons' acts would constitute patent infringement, or believed there was a high probability that the surgeons' acts, if taken, would constitute patent infringement and deliberately avoided confirming that belief.

I understand from reviewing the depositions of Arthrex's witnesses in this case, as well as Arthrex's responses to KFx's interrogatories and requests for admission, that there is no evidence Arthrex knew there was infringement. Likewise, there is no evidence that Arthrex

¹¹ I understand that it may not be appropriate for medical doctor expert witnesses such as myself and Dr. Ticker to opine on many issues related to inducement and contributory infringement as those issues largely depend upon the subjective state of mind and beliefs of fact witnesses and other facts that are not necessarily within the particular expertise of a medical doctor. I understand such testimony is best left to the fact witnesses themselves and other appropriate evidence. However, if the Court believes it is appropriate for Dr. Ticker and I to testify about these matters, I am prepared to do so pursuant to my opinion in this report.

intended infringement or subjectively believed that there was a high probability that surgeons using its accused SutureBridge and SpeedBridge methods directly infringe the KFx Patents. I also spoke with John Schmieding and he told me that, as the Arthrex representative charged with this responsibility, he believes such uses do not infringe the KFx Patents. Mr. Schmieding's and the Arthrex witnesses' beliefs of non-infringement are consistent with my opinions that there is no infringement.

I have also reviewed several opinions of counsel received by Mr. Schmieding from David Gaskey. CGO0000001-120; CGO0000121-249; CGO0000250-379; CGO0000380-619; CGO0000620-623. The opinions state that there is no direct infringement by surgeons and that KFx's Patents are invalid in view of prior art I identified in my expert report dated February 21, 2013. Mr. Gaskey also supplemented his original opinions after the Court's claim construction was issued. In it, he explained why he did not believe the claim construction impacted his original opinions regarding non-infringement. I also reviewed Mr. Gaskey's deposition during which he was questioned regarding all of his opinions.

In addition to Arthrex's subjective belief, I understand that Arthrex's reliance on the opinions of counsel regarding non-infringement and invalidity of the KFx Patents is also supportive of the fact that Arthrex did not intend infringement nor had a subjective belief that there was a high probability that surgeons were infringing the patent. It is also my opinion that Arthrex did not deliberately avoid learning of infringement. Rather than deliberately avoiding the issue, Arthrex conducted an investigation and then sought opinions of counsel which confirmed its belief that surgeons were not infringing and/or the KFx Patents were not valid.

Dr. Ticker's report uses a standard for determining inducement that is different from the one I was told to use. His standard requires that "Arthrex knew or should have known that its

actions would lead to actual infringement of at least one claim of the asserted patents.” Ticker Rep. at ¶ 84. As stated above, there is no evidence that Arthrex actually knew that the surgeon’s acts were infringing. For the same reasons described above, I also do not believe Arthrex “should have known” that the surgeons’ use of the accused methods would lead to actual infringement. There are several reasons why Arthrex has a reasonable belief that its identified methods do not infringe the KFx Patents and/or believe that the KFx Patents are invalid. Based on this, I do not believe it is reasonable to conclude that Arthrex “should have known” that the surgeon’s acts were infringing. Thus, I do not believe inducement could be found under KFx’ standard.

Dr. Ticker points to a couple of email exchanges between Arthrex employees and states that “it is reasonable to infer from Mr. Dreyfuss’ and Mr. Benavitz’s emails that they believed that claims other than 3 and 4 of the ‘311 Patent were infringed by Arthrex’s techniques.” Ticker Rep. at ¶ 94. Even if initial lay reactions of non-legal personnel were indicative of whether Arthrex believed it infringed a patent, which I understand it is not, Dr. Ticker ignores the fact that the substance of the emails shows that Mr. Benavitz and Mr. Dreyfuss did not believe Arthrex infringed and/or believed the KFx Patent was invalid. For example, Mr. Dreyfuss concludes one of his messages with “in other words, we don’t violate.” PDX 62 at ARTH_0082813. And Mr. Benavitz testified that he agreed with Mr. Dreyfuss’ conclusion. William Benavitz Depo. Tr. (Nov. 30, 2012) at 203-06. Thus, I disagree that it would be reasonable to infer that Mr. Benavitz and Mr. Dreyfuss believed there was infringement. In my opinion, the opposite is true. It would be reasonable to infer they did not believe there was infringement because that is what they stated.

Dr. Ticker also points to an email from Arthrex's patent counsel stating he intended to draft claims to cover KFx's method as supporting his opinion that Arthrex knew KFx infringed. Ticker Rep. at ¶ 94. As I understand it, Dr. Ticker has it backwards. The relevant question is whether Arthrex believed it infringed KFx's patent and not whether Arthrex believed KFx infringed Arthrex's patent. And Arthrex did not yet have a patent nor did it have any claims to compare with KFx's product as the claims were not yet drafted. In my opinion, this is not indicative of Arthrex knowing it infringed KFx's patent.

2. Arthrex does not contribute to infringing the KFx Patents

I understand that for Arthrex to be liable for contributing to the infringement of KFx's Patents, there must be a direct infringement. For the same reasons described above, I do not believe there is any direct infringement and therefore I do not believe Arthrex can be liable for contributing to direct infringement. If direct infringement is found, I also understand that for Arthrex to be liable for contributory infringement, among other things, it must be found that the accused products are not staple article of commerce with substantial non-infringing use and that Arthrex knows that the surgeons' use of the accused methods are infringing KFx's Patents. For the reasons described above, I do not believe that Arthrex had the requisite knowledge that its methods infringed KFx's Patents. I believe the opposite is true, that Arthrex believed, and still believes, that the use of its products does not infringe the KFx Patents and/or that the patents are invalid.

I understand that Dr. Ticker has opined that the SutureBridge and SpeedBridge kits (the only products where Arthrex is accused of contributory infringement) are not staple articles of commerce and do not have substantial non-infringing uses. I disagree. The accused anchors sold with the SutureBridge and SpeedBridge kits include PushLock, SwiveLock and Corkscrew

anchors. Each of these anchors, as Dr. Ticker acknowledges, are used in other non-infringing applications, such as labral and knee repairs. Ticker Rep. at ¶ 101. DDX 68; DDX 69; DDX 70; ARTH_0029938-70; KFX0019195-198; ARTH_1257764-69; ARTH_1257816-63; ARTH_1257808-815; ARTH_1257762-63; ARTH_1257800-807; ARTH_1257788-99; ARTH_1257782-87. Nonetheless, Dr. Ticker states “there is no reason to believe that the kits would have been used for procedures other than the infringing SpeedBridge and SutureBridge rotator cuff repair procedures.” Ticker Rep. at ¶ 101. He reasons that if only one or two anchors are used in another procedure, the other anchors in the kit would be wasted.

I disagree that a surgeon who is using the anchors found in the accused kits would choose to use fewer of those same anchors in a non-infringing rotator cuff procedure than he is already using in one of the accused methods. *Infra* at 64-73. That surgeon would likely use at least four anchor, and more likely greater than four anchors. And as described above, for both kits, there are non-infringing ways that the same anchors can be used even when using the SutureBridge and SpeedBridge methods. *Supra* at 36-43. Thus, I believe there are substantial non-infringing alternatives to the anchors sold with the accused kits.

D. Non-Infringing Alternative Techniques Available in 2009

I have been asked to opine on which non-infringing alternatives to the accused methods would have been available to surgeons in 2009 if the accused methods were not available at the time. I have also been asked to assume that Dr. Ticker’s assumption that surgeons who were using the accused methods at the time in 2009 would have continued to use Arthrex products.

Based on my 22 years of experience in conducting surgeries, my many years of teaching arthroscopic surgical procedures, and my general understanding of how surgeons in the field of arthroscopic surgery practice, it is my opinion that surgeons who were using the accused

methods in 2009 would have stayed with a method as similar as possible to the accused methods. Surgeon preference is a very important aspect of deciding which anchors and methods a surgeon would have used in place of the accused methods. Surgeons will generally try different methods and combinations of anchors until they arrive at a combination they are comfortable with. It is my opinion that once a surgeon has decided he is comfortable with a certain combination of anchors for a given type of tear, the surgeon is likely to stay with that combination unless there is a compelling reason to change.

For example, a surgeon who was using a four-anchor bridged construct such as the accused methods must be presumed to have had a specific reason for doing so at the time. It is possible that surgeon was using the accused methods due to the size and/or shape of the tear. He may have preferred to use the accused methods on larger tears, or it is possible he preferred to use the accused methods on smaller tears. Regardless, the reasonable assumption is that the surgeon has a specific reason for using the accused methods.

Other reasons the surgeon was using the accused methods could include the fact that he was more comfortable with the accused anchors for this specific procedure (e.g., rotator cuff or Achilles) than he was with other types of anchors. The surgeon's comfort level could be due to any number of factors including their ease of use, their reliability, the fact that the lateral anchors are knotless, the medial anchors are Corkscrew anchors that are inserted directly into bone, PushLock is a pound-in anchor, SwiveLock is a screw-in anchor and suitable for softer bone, the medial footprint for SutureBridge has added security with medial knots tied to the tissue, etc. It is also possible that the surgeon was comfortable with Arthrex's methods and anchors due to his relationship with Arthrex and its extensive surgeon education and training programs, which I've taken part in throughout the years, including acting as an instructor to other orthopedic surgeons.

It is also possible that the same surgeon might prefer other surgical methods and other anchors for different types of procedures and tear sizes/shapes. But as I understand it, Dr. Ticker's presumption is that surgeons were using the accused methods in the first place and then switched to another non-infringing alternative still manufactured by Arthrex. For the same reasons stated above, it is reasonable to assume, in such circumstances, that the same surgeon would look to replace the accused methods, for those surgeries in which he already believed the accused methods were most appropriate (for various reasons), with a method as similar as possible to the accused methods.

Methods similar to the accused methods could include the same or similar number of suture anchors placed in the same or similar locations in the bone. Such methods could also include bridged, or unbridged anchors. And those methods could include the same or similar types of suture anchors, for example, knotted or knotless anchors. I do not believe it is reasonable to assume this same surgeon would change much, if anything, from the accused methods if alternate methods are available that were similar to the accused methods.

All of the accused anchors, Corkscrew, PushLock and SwiveLock are commonly used in surgical procedures other than the accused methods. And by 2009, surgeons were very familiar with each of these anchors, their ease of use, versatility and reliability. For example, it was well known that these anchors were useful in the labrum, rotator cuff, Achilles tendon, as well as other areas of the body, including the knee. DDX 68; DDX 69; ARTH_0029938-70; KFX0019195-198; ARTH_1257816-63; ARTH_1257808-815; ARTH_1257762-63; ARTH_1257800-807; ARTH_1257788-99; ARTH_1257782-87. I understand that KFx does not dispute this. Tate Scott Depo. Tr. (Nov. 16, 2012) at 380-82. Thus, it is reasonable to assume that surgeons would have been familiar with, and comfortable with, the individual anchors and

the different ways they could be used aside from in the accused methods. Below, I describe several examples of alternate surgical methods that would have been available to surgeons in 2009.¹²

1. Bridged Double Row Methods

- a. SutureBridge and SpeedBridge methods in which tensioning of suture is performed only before the second anchor is inserted into the bone

As described above, I do not believe the eyelet portions of the accused PushLock and SwiveLock devices should be considered part of the anchors. Supra at 24-36. Therefore, when the eyelet is inserted into the bone, I do not believe that should be considered the second anchor being inserted into the bone, as that term is used in the claims of the KFx Patents. Supra at 34-36. Assuming Dr. Ticker is correct, and the eyelet is part of those anchors, I believe an obvious alternate method would be to use the accused SutureBridge and SpeedBridge methods but apply tension to the suture to compress the tissue to the bone only before the eyelet is inserted into the bone.

This is, of course, how tensioning is already achieved, as I described above. Supra at 36-43. The only tension applied after the eyelet is inserted into the bone hole is to “adjust” tension that was already applied with the eyelet outside of the hole, and even then, that tension is applied only “if necessary.” Supra at 36-43. This slight change in method -- where there is no adjustment of tension after the eyelet is in the hole -- would, in my opinion, have no meaningful impact on the efficacy of the repair and would allow surgeons to use essentially the same method and the same anchors they were already using and with which they are presumably comfortable.

¹² In addition to 2009, my opinions also apply to surgeons who would have been using the accused methods in 2010, 2011 and 2012. I believe such surgeons would have switched to the alternatives described below if the accused methods were no longer available.

Dr. Ticker does not identify this simple modification as a non-infringing alternative in his report. However, I believe a high percentage (approximately 75%) of surgeons who were using the accused methods in 2009 would have switched to this slightly modified, non-infringing, alternative method. The reason for this is that, as I explained above, the vast majority of surgeons will use as close an alternative as possible. This is the closest non-infringing alternative.

b. SwiveLock & FiberChain Knotless Repair

I understand that Dr. Ticker may believe (wrongly in my view) that this first alternative described above does not exist. Even if Dr. Ticker was correct, the next alternate method to which surgeons would turn is the SwiveLock & FiberChain knotless repair. ARTH_0686886-93. This repair is virtually identical to the accused methods in that two Corkscrew anchors are used medially and two SwiveLock anchors are used laterally where the two rows of anchors are bridged together by FiberChain suture material.

Just as with the accused SutureBridge method, the Corkscrew anchors are inserted directly into the bone under the tissue medially. Unlike SutureBridge, however, the Corkscrews in this alternate method are loaded with FiberChain and not FiberWire. FiberChain is a length of suture material that includes links of suture such as are included on a chain. The FiberChain is then passed through the tissue in the same manner that FiberWire is passed through the tissue in the accused methods. The FiberChain is then captured by a forked tip of the eyelet on the SwiveLock device such that the surgeon selects the link by which to capture the FiberChain. The surgeon can modify the tension in the suture by selecting different links in the chain; more links for looser tension and fewer links for greater tension. After the surgeon selects a link, the

eyelet is placed into the bone hole and the anchor body is then screwed into the bone hole to wedge the FiberChain between the anchor body and the bone wall and to fine tune the tension.

Although Dr. Ticker acknowledges this method is a non-infringing alternative, he states it would not be used in more than “de minimis numbers.” Ticker Rep. at ¶ 160. One reason he gives is that “there is no ability to fine tune tensioning to an optimum level.” Ticker Rep. at ¶ 159. He assumes that because the links are 6mm apart, “tension may only be adjusted to within 6mm.” Ticker Rep. at ¶ 159. I disagree. It has been my experience with previously performing this procedure that one can get within 1-2mm of the optimum tension. This 1-2mm difference is entirely acceptable and, in my opinion, would result in no clinical difference in surgical outcome as compared with the accused methods. Thus, although Dr. Ticker believes adoption of this method would be de minimis, his reasoning is incorrect and unjustified. It is my opinion that if Dr. Ticker is correct that the first alternative described above were not available, those same approximately 75% of surgeons would next turn to this alternative non-infringing method for the same reasons described above (because it is very close to SutureBridge and SpeedBridge).

2. Unbridged Double Row Methods

Another variation on the accused methods would be to use a double row construct without the two rows bridged together with suture. Such constructs have been well-known in the field for many years. ARTH_1257864-69; ARTH_1257881-88.

The same anchors currently used with the accused methods would be used for this alternate method. Based on my experience, and the scientific literature, it is not at all clear whether there is a great clinical difference between a bridged double row and an unbridged double row. See, e.g., ARTH_1257870-880; ARTH_1257889-894. Thus, surgeons would enjoy the benefits of using anchors with which they are already familiar.

Each of the examples described below are acceptable alternatives to the accused methods. Further, since the surgeon is presumably already familiar with the accused anchors, he is more likely to stay with the same anchors rather than using different anchors. And although four anchors are described for each of the examples below, in many instances, more than four anchors would be used for those surgeons who believe more anchors are needed to achieve the equivalent strength to a bridged double row construct. Although I do not believe the evidence convincingly shows that bridged double rows result in any greater compression and/or clinical results as compared with unbridged double rows, there are surgeons who do believe this is true. Therefore, in many instances where these unbridged double row methods were adopted, Arthrex would have sold more than four anchors to the same surgeon as compared with the accused methods, in which only four anchors are used.

While I believe that the vast majority of surgeons would opt for the alternative methods described above, I believe most of the remaining minority of surgeons (approximately 20%) would choose to go with one of the following unbridged double row methods because it is a similar procedure, uses the anchors with which the surgeon is already familiar and uses the same number of anchors that the surgeon has already determined to be appropriate for the repairs. I believe the approximately 20% of surgeons would be divided approximately equally between these three unbridged double row options (i.e., approximately 7% of surgeons would choose each method).

a. Unbridged SutureBridge alternate

In the case of a SutureBridge alternate, at least two 5.5mm Corkscrew anchors would be used medially and the attached FiberWire suture would be tied to the tissue above the medial anchors. At least two 4.5mm PushLock anchors would be used laterally just as they are in

SutureBridge. The suture would be tied to or passed through the lateral edge of the cuff and then the loose end of the suture would be threaded through the eyelet and tensioned to position the tissue as desired. The eyelet would then be placed into the bone hole and the anchor body would be inserted to wedge the suture between the anchor body and bone. The resulting construct is a double row repair using the same four anchors as are used in SutureBridge, but without the suture bridging the two rows.

b. Unbridged SpeedBridge alternate

In the case of a SpeedBridge alternate, at least two SwiveLock anchors (either 4.75mm or 5.5mm) would be used medially and the attached suture would be used to tie a knot to the tissue above each medial anchor. Either FiberWire or FiberTape could be used in this alternate method. The lateral anchors would also be at least two SwiveLocks (either 4.75mm or 5.5mm). The suture would be tied to or passed through the lateral edge of the tissue then the suture would be threaded through the eyelet and tensioned to position the tissue as desired. Then the eyelet would be placed into the bone hole and the anchor body screwed into the bone hole wedging the suture between the anchor body and the bone wall. This construct would use the same four anchors as are used in SpeedBridge, but without the bridged suture.

c. Unbridged SutureBridge/SpeedBridge hybrid

Surgeons who are already familiar with the anchors used in both the accused methods may alternatively opt for a hybrid of the two methods. For example, the surgeon may prefer to use at least two 5.5mm Corkscrew anchors medially, as in SutureBridge, but prefer to use at least two 4.75mm or 5.5mm SwiveLock screw-in anchors laterally, as in SpeedBridge. The sutures would be tied over the medial Corkscrews just as they are currently in SutureBridge. And the

lateral edge of the tissue would be secured with the SwiveLocks as described above for the unbridged SpeedBridge alternate. Here, the surgeon is using anchors he is already familiar with but only in a slightly different combination as that promoted by Arthrex.

3. Single Row Using Multiple Anchors

Another option available to surgeons in 2009 was a single row construct using multiple (i.e., four to six) anchors. The reason why surgeons would choose to use four to six anchors is because the surgeon is already presumed to have been using the accused methods, which have four anchors. Thus, regardless of the size or shape of the tear, the surgeon has already determined a four anchor construct is appropriate for the repair. It is reasonable to assume that if this same surgeon were suddenly unable to use the accused methods, and decided to use a single row construct, he would choose to use multiple anchors to best replicate the footprint and compression achieved by the accused methods. It is likely that the surgeon would use at least four anchors in a single row to replicate the strength of a double row with four anchors. In some cases, surgeons would use five or six anchors for the same tear which the accused methods are used to repair. I personally average five anchors in my single row repairs.

The construct would be prepared by inserting multiple anchors in a single row close to the lateral edge of the tissue in a zig-zag pattern. Some anchors would be underneath the tissue and other anchors would be adjacent to the edge of the tissue.

The anchors used in this unbridged single row method would be the same anchors used in the accused methods. They could be combinations of 5.5mm Corkscrew, 4.5mm PushLocks and 4.75mm and/or 5.5mm SwiveLock anchors depending upon surgeon preference. Each of these anchors have their advantages and would probably be split fairly evenly.

I believe a small minority of surgeons (approximately 2-3%) who were using the accused methods in 2009 would have opted for such a single row construct if the accused methods were no longer available. In those cases, I believe they would employ at least four anchors and more likely five or six anchors in their constructs for the same cases in which they would have been using the accused methods.

4. Bridged Double Row Using Knotted Anchors

Another alternate method available to surgeons in 2009 was the bridged double row method described by Dr. Millett in his article titled “Mattress Double Anchor Arthroscopic Rotator Cuff Repair.” This article was published in October 2004, and is described in detail in my prior report dated February 21, 2013. I believe this method would be chosen by a small minority of surgeons who wanted to maintain a bridged double row construct. I doubt it would have been widely adopted, however, in light of the other above-described bridged options that were available at the time.

Based on my experience both as a practitioner and as an instructor, it is my opinion that surgeons who were already using the accused methods in 2009 would have been comfortable using Dr. Millett’s method at that time. First, the Millett article was already well known for the past five years by that point. Those same surgeons would have already been familiar with using two medial Corkscrew anchors in the accused SutureBridge method, so it is reasonable to believe they would be comfortable with the two medial Corkscrews used in Dr. Millett’s method. The addition of two more lateral Corkscrew anchors would have been relatively simple for an experienced orthopedic surgeon in 2009 who was already using the accused methods.

I am also familiar with the knot tying required by Dr. Millett’s construct and I found it to be relatively simple to use. I also do not believe other surgeons would have found it difficult

since they were already tying arthroscopic knots when presumably using the accused SutureBridge method. I further understand Dr. Millett and his colleagues clinically used this same method many times dating back to at least 2003, thus by 2009, surgeons were already very familiar with the method and could have easily adopted it if they preferred a bridged double row construct. Nonetheless, in view of the more desirable options described above, I do not believe more than about 2-3% of surgeons would have opted for this methods if the accused methods were no longer available.

5. Response to Dr. Ticker's Opinions Regarding Non-Infringing Techniques

Dr. Ticker's opinion regarding non-infringing alternatives is based on a false premise. He assumes that surgeons who were using the accused methods would opt for alternate methods employing much fewer anchors and/or different anchors than those found in the accused methods if the accused methods were no longer available in 2009. I disagree that surgeons who were using the accused methods would choose a significantly different method, anchor type, and/or numbers of anchors. Rather, they would tend to gravitate toward a method, anchor type and number of anchors as similar as possible to the accused methods.

For example, Dr. Ticker assumes that surgeons will use a single anchor, single row repair for a small tear. Ticker Rep. at ¶¶ 174, 176. But he also necessarily assumes this same surgeon was using the accused methods for the same small tear. Ticker Rep. at ¶¶ 104, 131 ("I have been asked to determine which non-infringing rotator cuff repair techniques were available to surgeons in September 2009, and which of these non-infringing techniques surgeons would have been expected to perform if the infringing SpeedBridge and SutureBridge techniques were not available"). I disagree with this premise.

As explained above, a surgeon who was using the accused methods was using the accused methods for a specific reason(s). What is certain, is that the surgeon already decided to use a four anchor construct. That same surgeon would not switch to e.g., a single anchor, single row repair simply because the accused methods, which use four anchors, are not available. This is especially true when there are several alternative methods -- some of which Dr. Ticker does not acknowledge, or states that surgeons would not want to use them -- that much more closely resemble the accused methods, as described above. In short, surgeons would use a construct that most closely resembles the construct they were already familiar with, such as the ones described above.

Dr. Ticker also assumes the same surgeon who was using the accused methods would use two triple-loaded Corkscrew anchors for larger tears. Ticker Rep. at ¶¶ 137, 174. I disagree. It is my opinion that these surgeons would opt to use one of the bridged double row methods described above, or in the alternative, they would choose one of the unbridged double row methods.

If they were to use a single row method, they would not use triple loaded anchors. These surgeons would have known in 2009 that triple loaded anchors are very large (up to 6.5mm) and thus, only one or two can be used per repair. Triple loaded anchors are also very difficult, if not virtually impossible, to revise and fairly often can result in tuberosity fractures. These are several reasons why triple loaded anchors have not been successful in the market. For these reasons, I do not believe surgeons would tend to use triple loaded anchors when the same single and double loaded anchors with which they are already familiar (Corkscrew, PushLock and SwiveLock) were still on the market in 2009. Thus, for the small percentage of surgeons who

would have switched from the accused methods to a single row repair (2-3%), I believe they would have used the anchors as described above rather than a triple-loaded anchor.

Dr. Ticker also assumes that a certain percentage of surgeons who were using the accused methods in an arthroscopic procedure, would revert back to an open technique using a transosseous method. Ticker Rep. at ¶¶ 140-141, 177 and Exhibit F. I disagree. A surgeon who had become comfortable with arthroscopic surgery in 2009, as we assume is the case for a surgeon using the accused methods in 2009, would not revert back to an open transosseous procedure when there are many alternative methods available to him which can be done arthroscopically and with suture anchors. Dr. Ticker's assumptions are outdated and simply do not reflect the reality of the industry. Transosseous is a very difficult method and although it was once considered the "gold standard," that was long ago. Since then, implant driver repairs have become the gold standard. Thus, I do not believe any meaningful number of surgeons would opt to use an open transosseus method in place of the accused methods. This is especially true when one considers the other bridged double row methods available in 2009, as described above.

Dr. Ticker's analysis regarding different presumed approaches for a "high volume" surgeon versus a "low volume" surgeon also fails to recognize his original presumption that both types of surgeons were already comfortable using the accused methods arthroscopically in 2009. There is no reason to believe that a surgeon who was comfortable performing the accused methods, including arthroscopically tying medial knots over the Corkscrew anchors with SutureBridge, would be unable to perform any of the above described alternative procedures simply because Dr. Ticker labels him a "low volume," or "high volume" surgeon. Regardless of how many procedures a given surgeon performs, if he was using the accused methods, he is

obviously a proficient orthopedist and could have easily adapted to any of the above-described alternatives.

I also disagree with Dr. Ticker's premise that "low volume surgical centers would be used by 'low volume' surgeons and high volume surgical centers would be used by 'high volume' surgeons." Ticker Rep. at ¶ 126. Dr. Ticker bases his premise on a single article and fails to consider that a low volume surgical center can easily have very few high volume surgeons, whereas the high volume surgical centers can easily have many low volume surgeons. This assumption skews the rest of Dr. Ticker's data and analysis, at best, and renders it misleading, at worst.

Although Dr. Ticker acknowledges "high volume surgeons" in 2009 would generally be "technically capable of some of the non-infringing double row procedures," he then states that "they would have been significantly less preferred." Ticker Rep. at ¶ 120. To support this opinion, Dr. Ticker cites "increased cost" and "knot impingement." Ticker Rep. at ¶ 147. He then assumes that "low volume" surgeons would need to perform these double row procedures through an open approach. Ticker Rep. at ¶ 147.

I disagree that the above-described unbridged double row methods would be less preferred to an experienced orthopedic surgeon who is presumably already familiar with the accused methods and anchors. I also disagree that a "low volume" surgeon would need to perform these methods in an open procedure. We are presuming these surgeons – whether "low" or "high" volume – would have been using the accused methods in an arthroscopic procedure in 2009. The accused methods already require arthroscopic knot tying, proper placement of anchors into bone and suture tensioning just as the non-infringing double row alternative methods. To the extent a surgeon would be uncomfortable with a double row construct, it is my

opinion that same surgeon would tend to use a single row construct with at least four to six anchors.

Further, any cost increase for using unbridged double row methods over the accused methods would be negligible at best. It is also my experience that unless a surgeon actually owns a surgical facility, he is generally not going to take cost into account when deciding which surgical method to use for a given repair. He is much more likely to consider his comfort level with the method and with the anchors used in the method. I also disagree regarding knot impingement. Although knot impingement and crepitus have been a concern in the knee and intra-articularly on the shoulder, it has not been a significant concern in the shoulder with regards to rotator cuff repair, as this is really an extraarticular repair.

Dr. Ticker also opines that the transosseous equivalent surgical procedure using lateral Bio-Tenodesis screws is a non-infringing alternative. Ticker Rep. at ¶¶ 151-157. But this ignores the fact that KFx accused this same method of infringing the '311 Patent in this litigation. In its infringement contentions for the '311 Patent dated December 1, 2011, KFx listed the Bio-Tenodesis screw as an accused anchor used with the Achilles SutureBridge method. Plaintiff's Preliminary Infringement Contentions (Dec. 1, 2011) at 3. The Bio-Tenodesis screw is, in fact, promoted by Arthrex as an alternative to the lateral PushLock anchors in the Achilles SutureBridge surgical technique guide. ARTH_0029084-89 at 9088.¹³

¹³ I understand that KFx has recently indicated that it “will not be seeking a judgment of infringement,” allegedly “to narrow the issues and in view of the relative insignificance of the Achilles procedures versus the rotator cuff procedures.” ARTH_1257741. In my opinion, KFx is no longer pursuing the Achilles procedures because Arthrex promotes the use of the Bio-Tenodesis screw for the Achilles, and it learned that the work of Arthrex and Dr. ElAttrache with the Bio-Tenodesis screw renders the KFx Patents invalid, as I explained in my prior report dated February 21, 2013.

In order to accuse the use of Bio-Tenodesis screws in the Achilles SutureBridge of infringing the '311 Patent, KFx presumably believes that it operates the same way it believes the PushLock and SwiveLock anchors operate. That is, KFx must believe the suture coming from the first anchor is threaded through the suture eyelet at the end of the driver, then the eyelet is inserted into the bone hole and tensioned. That is, in fact, how the Bio-Tenodesis screw is used as the lateral anchor in the accused Achilles SutureBridge method. It is also how Bio-Tenodesis was used in the Arthrex/ElAttrache work, as I described in my prior report.

I also demonstrated this is the way Bio-Tenodesis was used as the lateral anchor in the Arthrex/ElAttrache work in a test I conducted for my prior report showing that a tension force is applied to the first strand of suture when the suture eyelet is inside the bone hole. The reason why the suture may be tensioned with the eyelet inside the bone hole is that the eyelet is made of suture instead of hard immovable plastic as with PushLock and SwiveLock. Since the eyelet is made of suture, the size of the eyelet can be varied by loosening the suture loop while the loop (eyelet) is at the bottom of the hole. This cannot be done with PushLock and SwiveLock as the eyelet is not expandable. This is why for PushLock and SwiveLock the first strand of suture is tensioned with the eyelet outside of the hole and tension is only adjusted, if necessary, when the eyelet is inside the bone hole. There are no such limitations with Bio-Tenodesis as the lateral anchor.

Dr. Ticker also misstates the facts as I understand them regarding the operation of Bio-Tenodesis and its early use as a lateral anchor in the Arthrex/ElAttrache work during 2003-2004. For example, he states that "most of Arthrex's and Dr. ElAttrache's early exploration involved utilizing a method for implantation which involved taking the suture which had been passed through the soft tissue, inserting it into the cannulation of the anchor driver, and bringing the

ends out proximally.” Ticker Rep. at ¶ 152. Even if this were true, and none of the exhibits to which Dr. Ticker cites support this statement, it ignores the work with Bio-Tenodesis screws described in the Arthrex/ElAttrache work. See e.g., Greenleaf Invalidity Report dated February 21, 2013 at 9-16, Exs. 12-23.

Dr. Ticker also points to a draft surgical technique guide for a method of using Bio-Tenodesis at the lateral edge of the rotator cuff. Ticker Rep. at ¶ 153. This technique is the one developed by Dr. Guanche and which is described in detail in my prior expert report dated February 21, 2013. See e.g., Greenleaf Invalidity Report dated February 21, 2013 at 24-26. He cites this guide for support that tensioning of the first strand of suture is done outside the bone hole and that it is not tensioned inside the bone hole. Ticker Rep. at ¶ 153.

As an initial matter, this is not the Arthrex/ElAttrache Work described in my prior report. It is also not using Bio-Tenodesis as a lateral anchor since this is not a double row construct, nor is it a bridged construct. There is only one anchor; the Bio-Tenodesis, so any description of how it operates as a stand-alone anchor is not relevant. In any event, Dr. Ticker also mis-states how the Bio-Tenodesis is used in this method. He does not acknowledge the fact that the guide states “the driver tip is inserted fully into the pilot hole and mattress suture tension is adjusted to position the lateral edge of the tendon at an anatomical position with the desired tension.” Ticker Rep. at Ex. 9, ARTH-69173. This clearly describes tensioning occurs after the suture eyelet is at the bottom of the bone hole.

Dr. Ticker then cites to Dr. ElAttrache’s January 21, 2004 surgery in which he used the Bio-Tenodesis laterally in a bridged double row construct. Ticker Rep. at ¶ 153. I described this surgery in detail in my prior report, including the fact that the first strand of suture from the medial anchor was threaded through the suture loop, then the suture loop was inserted into the

bone hole, and the first strand of suture was tensioned. See Greenleaf Invalidity Report dated February 21, 2013 at 14-15.

Dr. Ticker then cites to another single-row non-bridged application of Bio-Tenodesis and states that “it is very clear that no tensioning occurs after insertion of the driver into the hole.” Ticker Rep. at ¶ 153, citing ARTH_0005683. First, this is not a double row construct like the accused use of Bio-Tenodesis and the Arthrex/ElAttrache Work so it is of little to no value. But even if it was relevant, the video is not at all clear regarding when tensioning occurs and is, therefore, not supportive of Dr. Ticker’s opinion.

Dr. Ticker then points to several examples of knots referenced with the use of Bio-Tenodesis screws. Ticker Rep. at ¶¶ 154-155. He also states that “it is not clear that use of the Bio-Tenodesis without backup knots provides acceptable fixation.” Ticker Rep. at ¶ 155. First, many of the instances of Bio-Tenodesis use cited by Dr. Ticker are not in a double row construct. Rather, they are simply testing the holding strength of the Bio-Tenodesis screw when the suture is pulled in a vertical direction. Ticker Rep. at Exs. 13, 35, 36, 165, 166, 167. The forces acting on the suture are much different when the Bio-Tenodesis is a lateral anchor in a bridged double row construct as compared with the testing Dr. Ticker relies upon. These tests do not indicate how the Bio-Tenodesis would perform when used in a double row and are largely inapplicable.

Dr. Ticker does not point to any failures using Bio-Tenodesis in a double row bridging construct without knots. Dr. Ticker also does not acknowledge the Arthrex/ElAttrache Work in which the Bio-Tenodesis screws were used laterally without knots, as described in detail in my prior report. See, e.g., Greenleaf Invalidity Report dated February 21, 2013 at 9-16. And he also ignores that Bio-Tenodesis is used as an alternate knotless lateral anchor in the Achilles SutureBridge method. ARTH_0029084-89 at 9088.

Another reference Dr. Ticker relies upon an entirely different product and not the Bio-Tenodesis. Ticker Rep. at Ex. 31 (referencing the desire to create a knotless SutureBridge, since SutureBridge requires medial knots). This is also inapplicable.

Dr. Ticker then states that with Bio-Tenodesis, “tensioning takes place outside of the hole in a ‘guess and push’ fashion.” Ticker Rep. at ¶ 155. This ignores the fact that Dr. ElAttrache tensioned the first strand of suture with the suture eyelet inside the bone hole. ARTH_0030792-94. It also ignores the fact that when Mr. Cottle built his constructs in 2003, he did so by tensioning the first strand of suture with the suture eyelet inside the bone hole. ARTH_0004507-508. It also ignores the fact that the Achilles SutureBridge technique guide describes that Bio-Tenodesis can be used as an alternate lateral anchor in place of PushLock and does not instruct surgeons to tension in any way differently than the way described for PushLock. ARTH_0029084-89 at 9088.

Dr. Ticker then points to an internal sales bulletin which, according to Dr. Ticker, shows that tensioning occurs before the eyelet is placed in the hole. Ticker Rep. at ¶ 156, citing Ex. 29. As an initial matter, this is merely an internal shorthand document (referring to an outdated technique guide from 2007 (ARTH_0029072-9077)) internal short-hand document, and it is not at all clear when the tensioning takes place. Dr. Ticker is also wrong that customers know of this alleged procedure as Dr. Ticker ignores the fact that this is an internal document and “not intended for general distribution.” Ticker Rep. at Ex. 29. Thus, contrary to Dr. Ticker’s statement, customers did not see this document.

The Achilles SutureBridge document customers did see, however, instructs surgeons how to tension the suture when using PushLock (the same as with SutureBridge and SpeedBridge), and then states that the “Bio-Tenodesis Screw may be used for distal fixation” without any

different instructions for tensioning the suture. ARTH_0029084-89 at 9088. Thus, surgeons would have no reason to believe tensioning is done in any way different than it is done with PushLock (as described above).

Because KFx accused the use of Bio-Tenodesis with Achilles SutureBridge of infringing the '311 Patent, I do not believe Dr. Ticker's opinion regarding this method being a non-infringing alternative can stand.

E. Percentage of Accused Anchors Used in SutureBridge and SpeedBridge

I have been asked to opine on the approximate percentage of accused Corkscrew, PushLock and SwiveLock anchors sold by Arthrex that are actually used in one of the accused SutureBridge and/or SpeedBridge methods. My opinion is based only on the sizes of the accused anchors that are used in the accused methods. Thus, I focused on 5.5mm Corkscrews, 3.5, 4.5 and 5.5mm PushLocks and 4.75 and 5.5mm SwiveLocks. Each of these anchors are used in many other surgical procedures aside from the accused methods, including the other non-infringing rotator cuff repairs, such as single row or unbridged double rows, labral repairs and knee repairs. DDX 68; DDX 69; ARTH_0029938-70; KFX0019195-198; ARTH_1257816-63; ARTH_1257808-815; ARTH_1257762-63; ARTH_1257800-807; ARTH_1257788-99; ARTH_1257782-87.

Based on the practices of myself and my colleagues at my surgical center, Sports Medicine Oregon, and based on my experience with instructing others how to use the accused anchors in many different surgical procedures, I estimate that approximately 20% of the 3.5, 4.5 and 5.5mm PushLock anchors purchased by surgeons are used in a SutureBridge and/or SpeedBridge method. The vast majority, or approximately 80% of those sizes of PushLock are used for other non-infringing procedures such as, for example, unbridged double row repairs,

single row repairs, labral repairs and knee repairs. My opinion is based on my review of surgical procedures conducted with these anchors in my surgical center by myself and my colleagues. I believe my surgical center's use of the accused anchors is typical and on par with other surgical centers around the country, therefore I believe my uses of these anchors reasonably reflects the way other surgeons are using these same anchors.

Similarly, it is my opinion that approximately 50% of 5.5mm Corkscrews and approximately 50% of 4.75mm and 5.5mm SwiveLocks are used in the accused methods while approximately 50% of those anchors are used with other non-related, and non-infringing surgical methods such as those described above. These figures are also based on my review of the surgical records of my surgical center of myself and my colleagues.

F. Miscellaneous

I am familiar with the operation of the accused methods and anchors and may be asked to testify regarding the same at trial. I am also familiar with the operation of the alternative non-infringing techniques, and the anchors used in those techniques, described above and may be asked to testify at trial regarding those techniques. I am also familiar with KFx's SutureCross method, and the anchors used in SutureCross, and may be asked to testify at trial regarding the same as well as the general perception of SutureCross in the orthopedic field. I understand KFx states the SutureCross method was covered by the KFx Patents. Plaintiff's Preliminary Infringement Contentions, Dec. 1, 2011 at 4; Plaintiff's Preliminary Infringement Contentions as to Newly Asserted Patent Nos. 8,100,942 and 8,109,969, Apr. 9, 2012 at 5.

I may also be asked to provide live demonstrations of the accused products, the alternative techniques and/or SutureCross at the trial. I may also rely on visual aids and demonstrative

exhibits that demonstrate the bases for my opinions. A list of these exhibits will be provided prior to the trial.

IX. CONCLUSION

The opinions expressed in this report are based on the information currently available to me. I specifically reserve the right to formulate additional opinions and supplement my opinions as additional information becomes known to me, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, additional evidence submitted by either party prior to or during trial, and any additional reports of Plaintiff's experts permitted by the Court.

Dated: April 1, 2013


Jonathan E. Greenleaf, M.D.